Supreme Court, U.S.
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IN THE

SUPREME COURT OF THE UNITED STATES

UNITED STATES OF AMERICA
ex rel. ERDEM I. CANTEKIN,
Petitioner,

v.

UNIVERSITY OF PITTSBURGH, a non-profit Pennsylvania corporation; CHILDREN'S HOSPITAL OF PITTSBURGH, a non-profit Pennsylvania corporation; CHARLES D. BLUESTONE, an individual,
Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED FOR REVIEW

Revisiting the issue expressly reserved by this Court in footnote 4 of *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 946 (1997), do the "public disclosure" and "original source" provisions in the 1986 Amendments to the False Claims Act apply to a suit by a relator who, after the Amendments became effective, provided the Government with knowledge of pre-Amendment false claims?

PARTIES TO THE PROCEEDINGS

Petitioner

The United States of America ex rel. Erdem I. Cantekin. Cantekin is an individual and has no corporate affiliation.

Respondents

The University of Pittsburgh, a non-profit Pennsylvania corporation; Children's Hospital of Pittsburgh, a non-profit Pennsylvania corporation; and Charles D. Bluestone, an individual.

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STATEMENT OF CITATIONS OF REPORTS OF OPINIONS AND ORDERS

The Opinion of the Court of Appeals for the Third Circuit is reported at 192 F.3d 402. (Appendix A, pp. 1a-35a). After a diligent search, Petitioner has been unable to locate any official or unofficial report of any other Opinion or Order entered in this case.

STATEMENT OF JURISDICTION

The Judgment of the Court of Appeals, which affirmed the judgment of the United States District Court for the Western District of Pennsylvania entered February 9, 1998, and reversed the judgment of the District Court entered September 4, 1998 and September 9, 1998, was entered September 29, 1999. (Appendix B, pp. 36a-37a). The Order of the Court of Appeals denying rehearing was entered on May 22, 2000. (Appendix I, pp. 84a-85a) Accordingly, this Court has jurisdiction over this Petition pursuant to 28 U.S.C. § 1254(1).

STATEMENT OF STATUTORY PROVISIONS

31 U.S.C. § 3730 (1982 ed.). Civil actions for false claims

(b)(4) Unless the Government proceeds with the action, the court shall dismiss an action brought by the person on discovering the action is based on evidence or information the Government had when the action was brought.

31 U.S.C. § 3730 (Supp. 2000). Civil Actions for false claims

(d)(4)(A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

(B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

STATEMENT OF THE CASE

In 1979, Defendants, University of Pittsburgh, Children's Hospital of Pittsburgh, and Charles Bluestone applied to the National Institutes of Health (NIH) for research grants to determine the effectiveness of amoxicillin in combating ear infections in children. (Appendix A, pp. 3a-4a). The federally-funded research was intended to compare amoxicillin to placebo, *i.e.*, no drug at all. (Appendix J, pp. 137a-138a)

At the same time that he was submitting the NIH grant applications, Bluestone was conducting research funded by private pharmaceutical companies in which he ultimately concluded that other antibiotics performed as well as amoxicillin when used to treat pediatric ear infections. (Appendix A, pp. 4a; Appendix J, pp. 122a-123a) Bluestone also received substantial pharmaceutical industry funding to

perform research on other issues related to drug treatment of ear infections.

Bluestone, as principal investigator, was required to disclose all research support to the NIH on PHS Form 398, which is the grant application form. (Appendix A, pp. 24a-25a). For example, the 1979 version of the form, and all versions of the form thereafter, contained a page with a heading marked "Other Support." The instructions at the top of that page provide, in part:

> For each of the professionals named on page 2, list, in three separate groups: (1) active support; (2) applications pending review and/or funding; (3) applications planned or being prepared for submission. Include all Federal, non-Federal, and institutional grant and contract support. If none, state "NONE."

(Appendix A, p. 22a).

It was apparent to Bluestone's former colleague, Plaintiff Erdem I. Cantekin, that Bluestone needed to disclose to the NIH the pharmaceutical research grants he received to assess the effectiveness of amoxicillin specifically, and his financial ties to pharmaceutical companies generally. Not only was Bluestone receiving money from companies that manufactured the very antibiotic (amoxicillin) that he sought to research with Government funds, he had already staked his position that other drugs performed as well as amoxicillin. (Appendix J, pp. 137a-138a) Bluestone, therefore, should not have been the researcher evaluating whether amoxicillin was more effective than placebo because he had a vested interest finding that it was. (Appendix A, p. 25a) As Cantekin stated in his affidavit:

> In 1976, when Dr. Bluestone and I were applying for various NIH grants, I raised with Dr. Bluestone the question whether he, as principal investigator, should not be disclosing to NIH his other research support, especially from pharmaceutical companies. Dr. Bluestone replied that it was "none of their business," and that he was not going to tell the "federal feather merchants" because it would "muddy up the waters." Dr. Bluestone added that "idiots like Buckminster Ranney would not understand." Dr. Buckminster Ranney was an NIH-employee working with the National Institute of Neurological, Communicative Disorders, and Stroke ("NINCDS") with whom Dr. Bluestone had dealt.

(Appendix A, pp. 20-21). Bluestone made similar comments whenever Cantekin tried to revisit the issue. Ultimately, Bluestone received $17.4 million in NIH research grants, the last in January 1987, without disclosing (1) the $3.4 million in private pharmaceutical company grants that he had received to perform research in the same field (Appendix A, p. 4a), and (2) the speaking fees and expenses he had received from pharmaceutical companies, which exceeded $75,000 per year. (Appendix J, p. 124a)

Meanwhile, in October 1986, the Amendments to the False Claims Act became effective. Under prior law, a private person suing on his own behalf and on behalf of the United States to remedy false claims submitted to the Government could not prevail if the action was "based on evidence or information the Government had when the action was brought." 31 U.S.C. § 3730(b)(4) (1982 ed.). Under

the new law, the action could not proceed in the name of the private person if it was based upon "the public disclosure" of the conduct in certain arenas, unless the private person was "an original source of the information." 31 U.S.C. § 3730(d)(4)(A).

In May 1987, Cantekin came forward. He informed NIH of Bluestone's misdeeds. He also asserted that Bluestone's research was compromised by his close ties to the drug industry. (Appendix A, pp. 4a-5a).

After NIH took no action, Cantekin testified before the United States House of Representatives' Committee on Government Operations. (Appendix A, p. 5a). The House Report, entitled *Are Scientific Misconduct and Conflicts of Interest Hazardous to Our Health?*, H.R. Rep. No. 101-688, 101st Cong., 2d Sess. (Sept. 10, 1990), described the Bluestone affair in detail, blistering the University of Pittsburgh and the NIH for its laissez-faire attitude. (Appendix J, pp. 86a-143a) The findings of the House Report were also confirmed by the newly-created Office of Scientific Integrity within NIH, which recommended that Bluestone be placed on administrative oversight for five years as punishment for "having failed to disclose his private pharmaceutical company research to NIH and having analyzed the data from NIH-funded research in a manner biased towards the effectiveness of the antibiotics he had evaluated with public monies." (Appendix A, pp. 5a-6a; Appendix J, pp. 138a-139a)

Bluestone never received another nickel from NIH after this episode. His findings, moreover, contributed to a national epidemic of antibiotic misuse and drug-resistant infections. The Government continues to spend millions of dollars in an attempt to reverse the trend.

Cantekin, on behalf of himself and the United States, filed this action in 1991 against University of Pittsburgh, Children's Hospital of Pittsburgh, and Bluestone (collectively "Bluestone" or "Defendants") under the *qui tam* provision of the False Claims Act. 31 U.S.C. § 3730. Jurisdiction was based on 28 U.S.C. § 1331. Cantekin alleged, among other things, that the Defendants received nearly $18 million in federal funds by submitting false or fraudulent claims, i.e., they would not have received any grant money had Bluestone's ties to the pharmaceutical industry been properly disclosed. The Government declined to intervene; therefore, Cantekin conducted the action.

On June 20, 1996, the District Court denied Defendants' motion for summary judgment. In particular, the Court held that there was a triable issue of material fact "whether the NIH was aware, in deciding to award a grant to support defendants' research in treating otitis media (middle ear disease), that Dr. Bluestone had received and continued to receive financial grants from private pharmaceutical companies in support of the same or similar research." (Appendix H, pp. 82a-83a) Four months later, this Court agreed to hear *Hughes Aircraft Co. v. United States ex rel. Schumer*, 519 U.S. 926 (1996), to determine whether the 1986 Amendments to the False Claims Act applied retroactively.

This Court, on June 16, 1997, unanimously answered that question in the negative because retroactive application of the Amendments would have resurrected a stale claim. More specifically, the allegedly false claim and the Government's knowledge of the alleged fraud existed before the 1986 Amendments took effect. 520 U.S. 939, 945 (1997). On the other hand, this Court's retroactivity analysis expressly left open the question of how to apply the Amendments if the

false claim was submitted prior to 1986, but the Government did not have the information on which the suit is based until after 1986:

> Because both the allegedly false claim submission and the disclosure to the Government of the information about that submission occurred prior to the effective date of the 1986 amendments, we need not address which of these two events constitutes the relevant conduct for purposes of our retroactivity analysis.

Id. at 946 n.4.

Defendants renewed their motion to dismiss in light of *Hughes Aircraft*. Among other things, they contended that Cantekin could not recover for false claims submitted prior to the effective date of the Amendments because his suit was based upon information the Government had when he filed suit in 1991. The District Court, when revisiting this argument it once rejected, did not consider the information supplied by *Cantekin* because he submitted his information after the effective date of the Amendments and he clearly was an "original source." Nevertheless, the Court credited and gave dispositive weight to the affidavit of an NIH functionary not involved in the application review process in which she swore that she knew all about Dr. Bluestone's pharmaceutical industry ties from the very beginning. (Appendix G, pp. 68a-81a) After denying reconsideration, (Appendix F, pp. 53a-67a) the Court entered final judgment against Cantekin on October 2, 1998. (Appendix D, pp. 39a-42a)

Cantekin filed a timely appeal. With respect to allegedly false claims submitted prior to the date of the

Amendments, the only issues briefed or argued were the breadth and depth "of information the Government had" without regard to Cantekin's disclosures. This issue was "sharply dispute[d]." (Appendix A, p. 14a). Rather than resolving it, the Court of Appeals *sua sponte* decided the issue reserved by this Court in *Hughes Aircraft* footnote 4 and held that the relevant conduct for purposes of retroactivity analysis is, in all circumstances, the date of submission of the false claim. (Appendix A, pp. 16a-17a) Therefore, the Court held that Cantekin destroyed his ability to sue by coming forward after the Amendments became effective, even though those Amendments were designed to encourage original sources to report fraud on the Government and still preserve their ability to sue. Although the Court permitted Cantekin to proceed with the suit to remedy post-1986 fraud (Appendix A, pp. 19a-34a), Bluestone received more than 90% of the federal funds based upon false claims submitted before the effective date of the Amendments.

The Third Circuit's decision, by its express terms, declines to follow the Ninth Circuit's decision in *United States ex rel. Anderson v. Northern Telecom, Inc.*, 52 F.3d 810 (9th Cir. 1995), creating an inter-circuit split. (Appendix A, p. 19a). The Third Circuit, however, did not comment on the intra-circuit split within the Ninth Circuit on this issue. *See United States ex rel. Lujan v. Hughes Aircraft Co.*, 162 F.3d 1027, 1031 (9th Cir. 1998) (ostensibly overruling *Northern Telecom sub silentio* based upon this Court's decision in *Hughes Aircraft*).

REASONS FOR GRANTING THE WRIT

The Court of Appeals Violated the Cardinal Principal of Retroactivity Analysis That the Legal Effect of Cantekin's Conduct Should Be Assessed Under the Law That Existed When His Conduct Took Place.

It remains the touchstone of retroactivity analysis that "the legal effect of conduct should ordinarily be assessed under the law that existed when the conduct took place." *Landgraf v. USI Film Prods.*, 511 U.S. 244, 265 (1990), *quoting Kaiser Alum. & Chem. Corp. v. Bonjorno*, 494 U.S. 827, 855 (1990) (Scalia, J., concurring). The Third Circuit in this case, and the Ninth Circuit in *Lujan*, despite the clarity of its prior decision in *Northern Telecom*, ignored this simple and salient principle. They also ignored *all* of this Court's recent retroactivity decisions, *e.g.*, *Martin v. Hadix*, 527 U.S. 343 (1999) and *Lindh v. Murphy*, 521 U.S. 320 (1997), except for *Hughes Aircraft*. In the process, the Courts so seriously contravened the tenets of *Landgraf* that this Court should issue the writ.

I. Congress Clearly Intended the 1986 Amendments to Apply to Cantekin's Conduct.

Retroactivity analysis is a two-step process. Step One: Does the statute contain an express command on the issue of retroactivity? If so, the Court must apply the mandate. *Martin*, 527 U.S. at 352. Even if the statute does not contain an express command, the structure of the statutory scheme may reveal clear a "clear congressional intent" to apply the

law in a certain way, which has the same effect as an express command. *Id.* at 354, *quoting Landgraf*, 511 U.S. at 280.[1]

Hughes Aircraft addressed Step One specifically: "Nothing in the 1986 amendment evidences a clear intent by Congress that it be applied retroactively, *and no one suggests otherwise.*" 520 U.S. at 946 (emphasis added). One sentence later, the Court dropped footnote 4 to make clear that its analysis did not apply to disclosures made after the effective date of the Amendment.

Cantekin in this case *is* suggesting otherwise. Neither the Third Circuit nor the Ninth Circuit in *Lujan* even attempted to address Step One. Only the Ninth Circuit in *Northern Telecom* addressed this issue. 52 F.3d at 814 (Congress told the relator "what to do in the future"). In fact, the structure, language and history of the False Claims Act leave no doubt that the 1986 Amendments were intended to apply to Cantekin's disclosures, regardless of when the false claim was submitted.[2]

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[1] *Landgraf* appeared to create a three-step inquiry: (1) is there an express command; if not, (2) does the statute have retroactive effect; if so (3) did Congress clearly intend retroactive application? 511 U.S. at 280. *Hughes Aircraft* and *Martin* melded questions one and three. *Martin*, 527 U.S. at 353-57; *Hughes Aircraft*, 520 U.S. at 946.

[2] Footnote 4 of *Hughes Aircraft* may have been calculated to protect the vitality of *Northern Telecom*. This Court was clearly aware of *Northern Telecom* because the Ninth Circuit's decision in *Hughes Aircraft* specifically distinguished *Northern Telecom*. *United States ex rel. Schumer v. Hughes Aircraft*, 63 F.3d 1512, 1517 n.1 (9th Cir. 1995), *vacated and remanded* 520 U.S. 949 (1997).

The original *qui tam* provision appeared in Sections 3491 and 3493 of the Act of March 2, 1863, 12 Stat. 696 (31 U.S.C. § § 232, 234 (superseded)). Under that version of the statute, "any" person was authorized to bring suit on behalf of the United States, even someone who did nothing more than read a government indictment. *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 546 (1943). Congressional response to the *Hess* decision was swift, furious, and intended to eliminate parasitic lawsuits brought by strangers to the fraudulent behavior. Accordingly, Congress amended the statute to prohibit relators from bringing actions "based on evidence or information that the government had at the time the action was brought." 31 U.S.C. § 3730(b)(4) (1982 ed.). The Senate version of the 1943 bill understandably noted that the bar would not apply if the relator was the "original source" of the information. But, "[w]ithout explanation, the resulting conference report dropped the clause regarding original sources of allegations and courts have since adopted a strict interpretation of the jurisdictional bar as precluding any *qui tam* suit based upon information in the Government's possession, despite the source." S. Rep. No. 345, 99th Cong., 2d Sess. 12, *reprinted in* 1986 U.S. Code Cong. & Admin. News 5266, 5277.

It soon became apparent, however, that the 1943 amendments swung the pendulum too far against relators. The perverse result of the 1943 amendments was to discourage people from reporting fraud to the Government and instead file suit because disclosure eliminated the ability to sue. Perhaps the most troubling by-product of the 1943 amendments was reflected in *United States ex rel. State of Wisconsin v. Dean*, 729 F.2d 1100 (7th Cir. 1984), in which the State of Wisconsin, as an original source, discovered a fraud on the Government, was required by federal law to report the fraud, and then was barred from suing as a *qui tam*

plaintiff. The 1986 amendments specifically were intended to rectify this unreasonable and unintended result. *See generally United States ex rel. Stinson v. Prudential Ins.*, 944 F.2d 1149, 1153-54 (3d Cir. 1991); *id.* at 1162-68 (Scirica, J., dissenting) (majority and dissenting opinions exhaustively reviewing the historical context of the 1986 Amendments); *cf. Rivers v. Roadway Exp., Inc.*, 511 U.S. 298, 311 (1994) (noting that a restorative purpose is relevant when considering Congressional intent).

The 1986 Amendments shouted out to original sources: "Come forward now and expose Government fraud!" It is simply an irrational interpretation of legislative intent, based upon the language, structure, and history of the False Claims Act, to suggest that Congress meant to say: "We want you to come forward, but anything you tell us will still defeat your ability to sue as a relator. Wait a couple of years to discover post-1986 fraud, and then come forward."

The result achieved by the Court of Appeals turns Congressional encouragement into Congressional entrapment. Under the old regime, the case law provided a whistleblower with notice that disclosure to the Government would bar a later *qui tam* action. The text, policy, and history of the 1986 Amendments, however, could only lead a whistleblower like Cantekin to conclude that no longer would informants be penalized for coming forward; their conduct would be judged under the existing law. Nevertheless, under the Third Circuit's approach, the 1986 Amendments *compounded* the perversity of the old regime by luring whistleblowers to report pre-Amendment false claims with impunity. Congress is in the business of remedying fraud, not committing it. *Cf. Ingalls Shipbuilding, Inc. v. Director, OWCP*, 519 U.S. 248, 261 (1997) (statutes should not be interpreted in a manner that leads to "absurd" or "glaringly unjust" results).

This Court need go no further than Step One. Applying "normal rules of construction," *cf. Lindh*, 521 U.S. at 326, Congress clearly intended a relator's post-Amendment conduct to be governed under post-Amendment standards.

II. Applying the 1986 Amendments to Cantekin Would Not Have Retroactive Effect on Bluestone Because Cantekin Had a Viable Claim Before the 1986 Amendments Became Effective.

If Congress has not clearly stated its intention concerning retroactive application of new law, courts must proceed to Step Two and engage in a "common sense, functional judgment about 'whether the new provision attaches new legal consequences to events completed before its enactment.'" *Martin*, 527 U.S. at 357-58, *quoting Landgraf*, 511 U.S. at 270. *Hughes Aircraft* determined that the 1986 Amendments would attach new legal consequences to the allegedly false claims submitted prior to their effective date *if* the case were barred under prior law:

> [T]he 1986 amendment eliminates a defense to a *qui tam* suit - prior disclosure to the Government - and therefore changes the substance of the existing cause of action for *qui tam* defendants by attaching a new disability, in respect to transactions or considerations already past.

520 U.S. at 948 (quotation omitted). It also held that the 1986 Amendments create a new cause of action by private parties who would have been out of court under prior law:

> Prior to the 1986 amendment, respondent's *qui tam* action was completely barred because of

> Hughes' disclosure to the Government of information about its claim submissions. The 1986 amendment would revive that action, subjecting Hughes to previously foreclosed *qui tam* litigation, much like extending a statute of limitations after the pre-existing period of limitations has expired impermissibly revives a moribund cause of action.

Id. at 950. Therefore, on the facts of that case, *Hughes Aircraft* refused to apply the 1986 Amendments to pre-Amendment false claims because of the retroactive effect the Amendments would have had on a dead cause of action.

Nevertheless, footnote 4 suggests, and the Ninth Circuit acknowledged in *Northern Telecom*, that the analysis is quite different when the whistleblower provides information to the Government after the effective date of the Amendments. That circumstance requires a re-evaluation of "familiar considerations of fair notice, reasonable reliance, and settled expectations," *Martin*, 527 U.S. at 358, and leads ineluctably to a finding of no retroactive effect.

Consider the following. When midnight passed on October 26, 1986 - the effective date of the Amendments -- the defendant in *Hughes Aircraft* understandably slept easy. No suit had been filed and the Government knew everything. The case was barred. When Schumer tried to use the 1986 Amendments to disturb the defendant, this Court unremarkably told the defendant to go back to sleep, it's only a bad dream.

Bluestone, on the other hand, was pacing the floors on October 26, 1986. Five minutes before midnight on October 26, 1986, Cantekin could have brought a viable *qui tam* suit

because Cantekin, at that time, had not made any disclosure to the Government at all. He did not make disclosures until May 1987 and thereafter. If Cantekin had filed suit five minutes before midnight on October 26, 1986, Bluestone could not have asserted a "Government knowledge" defense based upon anything Cantekin had done. Bluestone had no settled expectations that he was in the clear prior to October 26, 1986 because Cantekin said nothing to the Government until eight months later. He was on notice in October 1986 and thereafter that his conduct could subject him to liability under the False Claims Act, *and that Cantekin could sue him as a relator.*[3]

Cantekin decidedly is not asking this Court to revive a stale claim. This Court explained in *Hughes Aircraft* that applying the 1986 Amendments to a previously barred claim is comparable to "extending a statute of limitations after the pre-existing period of limitations has expired impermissibly

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[3] As the Ninth Circuit stated in *Northern Telecom*:

> Congress changed the consequences of Mr. Anderson's conduct, not Northern Telecom's, in 1986. Had Mr. Anderson gone to the FBI with his information before the 1986 amendment, his subsequent claim would have been barred by his own disclosure. After the amendment, his disclosure to the FBI did not bar his claim. Because Mr. Anderson acted after the amendment, and the amendment changed the consequences only of his conduct, application of the amendment to his conduct is prospective, not retroactive.

52 F.3d at 815-16 (citation omitted).

revives a moribund cause of action." 520 U.S. at 950, *citing Chenault v. United States Postal Serv.*, 37 F.3d 535 (9th Cir. 1994). Cantekin's case, however, was not barred in October 1986, and, using this Court's analogy, there is nothing improper with extending a statute of limitations if the pre-existing period of limitations has *not* expired. *Chenault*, 37 F.3d at 538. This case is therefore no different than *Bradley v. School Board of Richmond*, 416 U.S. 696 (1974), in which this Court permitted retroactive application of a statute authorizing an award of attorneys' fees to the prevailing party in school desegregation cases precisely because the defendant was already exposed to an award of attorneys' fees under different principles. *See Martin*, 527 U.S. at 359-60 (discussing *Bradley*).

Whether the phrase used is "relevant conduct," *Hughes Aircraft*, 520 U.S. at 946 n.4, the "retroactivity event," *Martin*, 527 U.S. at 363 (Scalia, J. concurring), or a more general reference to "familiar considerations of fair notice, reasonable reliance, and settled expectations,"[4] the result remains the same. An original source with information about false claims had a reasonable expectation in 1987 that he could disclose that information to the Government and not lose his *qui tam* rights, regardless of when the false claims were submitted. Congress intended the 1986 Amendments to regulate Cantekin's conduct, not Bluestone's. Focusing properly on Cantekin's May 1987 disclosures to the Government, it is apparent that the 1986 Amendments do not have retroactive effect.

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[4] *See also Northern Telecom*, 52 F.3d at 814 ("The issue is, prospective to what?"); *Martin*, 527 U.S. at 362 (Scalia, J. concurring) ("[T]he key question [is]: retroactive in reference to what?").

CONCLUSION

For the foregoing reasons, a writ of certiorari should issue to review the judgment of the United States Court of Appeals for the Third Circuit entered in this case on September 29, 1999.

Respectfully submitted,

/s/_____

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APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

[Filed September 29, 1999]

No. 98-3552

UNITED STATES OF AMERICA, ex rel. ERDEM I. CANTEKIN, an individual

v.

UNIVERSITY OF PITTSBURGH, a non-profit Pennsylvania corporation; CHILDREN'S HOSPITAL OF PITTSBURGH, a non-profit Pennsylvania corporation; CHARLES D. BLUESTONE, an individual;

United States of America, ex rel. Erdem I. Cantekin,
Appellant

(Amended pursuant to Clerk's order dated 1/7/99)

On Appeal from the United States District Court
for the Western District of Pennsylvania

Court of Appeals Opinion - 9/29/99

(D.C. No. 91-cv-00715)
District Judge: Hon. Donald E. Ziegler, Chief Judge

BEFORE: NYGAARD, STAPLETON and COWEN,
Circuit Judges

OPINION OF THE COURT

COWEN, *Circuit Judge*.

This case concerns a medical researcher's failure to disclose his industry funding on a number of grant applications that he submitted to the National Institutes of Health (NIH). The undisclosed funding included several million dollars from pharmaceutical companies making the drugs that the NIH paid the researcher to evaluate.

On this appeal we must determine when a private party can properly bring a suit under the False Claims Act's *qui tam* provision, 31 U.S.C. §3730(b), which allows an individual to sue on the government's behalf for damages caused by another party's false claims. Congress has changed several times the rules limiting when a private party can bring a *qui tam* suit under the False Claims Act. We must resolve which of two versions of the Act apply to the various grant applications that the researcher submitted to the NIH and what effect each version has on the claims it controls.

A recent Supreme Court decision, *Hughes Aircraft Co. v. United States ex rel. Schumer,* 520 U.S. 939, 117 S.Ct. 1871 (1997), discussed the retroactivity of the 1986 Grassley Amendments, Congress's latest change to the Act's *qui tam*

rules. Applying *Hughes*, the District Court concluded that Erdem Cantekin, the appellant, could not pursue *qui tam* claims based on grant applications that Charles Bluestone, the researcher and appellee, submitted before October 27, 1986. Although our reasoning differs from the District Court's, we will affirm its ruling on these applications submitted in 1986 or earlier.

For Cantekin's remaining *qui tam* claim, which was based on an application submitted after the effective date of the 1986 amendments, the District Court granted summary judgment in favor of Bluestone and the other defendants because the Court concluded that Bluestone did not knowingly omit his industry funding from the application. Contrary to the District Court, we conclude that genuine factual disputes preclude summary judgment on whether Bluestone knowingly submitted a false claim.[1]

I

Both the appellant, Erdem Cantekin, and the appellee, Charles Bluestone, are professors of otolaryngology at the University of Pittsburgh's medical school and have worked together on research since the early 1970s. As part of their collaboration, they created the Otitis Media Research Center

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[1] The University of Pittsburgh and Children's Hospital of Pittsburgh joined Bluestone in applying for various grants and were also named as defendants. For convenience, we have referred throughout our opinion to the claims against Bluestone, but our analysis applies equally to the other named defendants.

to investigate acute otitis media and otitis media with effusion, two ear diseases common in children.

Much of the research they conducted together focused on testing the effectiveness of various antibiotics, such as amoxicillin, in treating the different types of otitis media. This research was particularly significant because while the drugs are widely used, controversy continues about the desirability and effectiveness of using antibiotics for these conditions. Not only are there medical reasons for worrying about unwarranted use of antibiotics, but also according to Cantekin's brief, the public spends over half a billion dollars annually buying antibiotics to treat the various forms of otitis media.

To pursue the research on antibiotics, Bluestone submitted numerous grant applications to the NIH throughout the 1970s and 1980s and ultimately was awarded approximately $17.4 million. At the same time, Bluestone began receiving funding from various pharmaceutical companies to test the effectiveness of their antibiotics in treating otitis media. Collectively, this industry funding totaled approximately $3.4 million.

Cantekin claims that as early as 1976, he raised with Bluestone his failure to list his industry funding on his NIH grant applications, but Bluestone allegedly brushed him off, saying that he was not going to tell the "federal feather merchants" because it was "none of their business" and would "muddy up the waters." App. at 523. Cantekin also disputed Bluestone's interpretation of research results, in particular the results of several industry-funded studies.

In May of 1987, Cantekin wrote to the NIH complaining about Bluestone's conduct, but the NIH chose to take no action, instead deferring to an investigation conducted by the University of Pittsburgh. When the university announced on June 22, 1987 that it had cleared Bluestone of any wrongdoing, the NIH dropped the matter. Dissatisfied with the university's investigation and with the NIH's reliance on it, Cantekin later testified before the United States House of Representatives at hearings investigating scientific fraud in federally funded research.

While the congressional report from the hearings was pending, the NIH decided to conduct its own inquiry into Bluestone's conduct. The resulting report by Howard Hyatt, then director of the NIH's Division of Management Survey and Review, concluded that Bluestone and the Otitis Media Research Center had "not generally disclosed to NIH the extent of its industry-sponsored research." App. at 508. But Hyatt continued that since the grant instructions were ambiguous, Bluestone's conduct was excusable. Hyatt also rejected Cantekin's claim that Bluestone's research results were biased.

On September 10, 1990, the House released its report, which discussed ten cases where grant recipients had engaged in misconduct. *See* H.R. Rep. No. 101-688, *Are Scientific Misconduct and Conflict of Interest Hazardous to Our Health?* 19th Report, Committee on Government Operations, 101st Cong., 2d Sess. (Sept. 10, 1990). Bluestone's case was included among the ten. The House report excoriated both the University of Pittsburgh's investigation as well as Hyatt's report and challenged many of their findings. Several months later, in December of 1990, the NIH issued a new report by

the agency's recently created Office of Scientific Integrity (OSI), which had reopened the agency's inquiry into Bluestone's conduct. Dr. Suzanne Hadley, then Acting Deputy Director of OSI, was in charge of this second NIH investigation. Her affidavit explained that the OSI report

> recommended that the Director of NIH require that Dr. Bluestone be place on a period of five years of administrative oversight for having failed to disclose his private pharmaceutical company research to NIH and having analyzed the data from NIH-funded research in a manner biased towards the effectiveness of the antibiotics he had evaluated with public monies.

App. at 481.

To illuminate how Bluestone's failure to disclose his industry funding could have affected the NIH's approval of his grants, Cantekin provided the following overview of the application process. Applications are first assigned to one of several institutes within the NIH. In Bluestone's case, his applications were sent to the National Institute for Neurological, Communication Disorders, and Stroke, which then forwarded them to the Communication Disorders Review Committee (CDRC), one of the review committees within the institute. A review committee is the body primarily responsible for evaluating the merits of applications like Bluestone's. Each review committee is composed of experts who are not NIH employees and are paid per diem for evaluating the applications. Frequently, the review committee

members have themselves received NIH grants in conducting their own research.

The review committee takes two votes on an application. The first vote is to "approve" or "disapprove" the requested grant; receiving approval at this stage, however, does not assure that the application will be funded. The application may still be rejected based on the second vote, which establishes a "priority score." To determine the priority score, each member of the review committee gives the proposal a score between 1, for the highest priority, and 5 for the lowest. Each member's score is then added together, the total is divided by the number of members, and the resulting average is multiplied by 100, yielding the final priority score. Thus, the highest priority score possible is 100 and the lowest 500.

In 1984, Bluestone and Children's Hospital of Pittsburgh submitted an application to extend an earlier grant by five years. Their first request for an extension received a priority score of 154 and was not funded, but later Bluestone and the Otitis Media Research Center submitted a revised application that received a priority score of 131, which was good enough to receive funding.

If we combine the NIH's method of calculating the priority score and the rough guideline that an application with a score of 154 or higher would not receive funding, at least around the time that Bluestone's application was considered, we can see that one or two members can easily raise an applicant's priority score above the cut-off for funding. For example, votes of 1, 1, 1, 1, and 5 yield a priority score of 180; and votes of 1, 2, 1, 1, and 3 yield a score of 160. Even

votes of 1, 1, 1, 1, and 3 could place an applicant on the edge of rejection with a priority score 140.

After the priority vote, an executive secretary, who functions as a staff member for the committee, writes a report describing the review committee's deliberations and submits the report to the Council of the Institute.' The council receives applications from the various review committees within the institute and makes the final determination of which applications will be funded. Council members, like the review committee members, are not NIH employees and are chosen for their expertise in their field. Unlike the review committee members, however, council members are appointed to serve for four-year terms.

Once a multi-year grant has been approved for funding, NIH assigns the grant to a "program administrator," who is in charge of administering the grant. Each year the grant's principal investigator, Bluestone in our case, and the grantee institution must submit a special continuing application, or progress report. These progress reports are "noncompetitive" in that funding during the allotted time has already been approved. The purpose of the progress reports is to informed the NIH of how the research is advancing, identify the amount of the budget for the next year, and provide information about key personnel engaged in the research.

Two of the five members of an NIH review committee that voted to approve one of Bluestone's grants stated in affidavits that if they had known about his industry funding, it would have affected their decision. Dr. Perkell, one of the review committee members, said that Bluestone's undisclosed

industry funds were not "common knowledge." He continued:

> [I]t is my opinion that had Dr. Bluestone disclosed his relationships with the private pharmaceutical industry, the competing renewal application of NS 16337 which came before the Review Committee of which I was a member would have been evaluated more critically with regards to: demands on investigator time, possible conflicts of interest, the effects of bias on the value of the proposed studies, safeguards in the study design to ensure unbiased interpretation and evaluation of the results of the proposed studies. The more critical evaluation would have had an impact on the recommendation for approval and on the priority score. The impact on the priority score I gave would have been material and negative. In my opinion, based on my knowledge of past behavior of my fellow members of the Review Committee in evaluating and assigning priority scores to several hundred other applications the impact on the overall priority funding score would have been material and negative.

App. at 473-74.

Dr. Schwartz, the chair of the review committee, also stated in an affidavit that she was unaware of Bluestone's industry funding and that had she known, it would have had a "material and negative" effect on her evaluation of the

application. She explained that a researcher who receives substantial funding from a pharmaceutical company can be subtly biased in favor of finding that the company's drugs are effective. Disclosure of this potential source of bias is important to reviewers even if the grant might be ultimately approved since the review committee might not approve the application until certain additional safeguards are implemented. "When bias, or potential bias, are revealed by disclosure of a funding source with a vested interest in the outcome of the research, reviewers are alerted to look for defects in the experimental design which could compromise the work proposed." App. at 1125. Elsewhere, she explained:

> A bias experimenter can still perform valid work, but the experiments must be carefully designed so that enrolled patients are randomly assigned to different test groups, objective criteria for measuring function are used, and both subject and observer are blinded as to which experimental condition (i.e. new drug, current standard drug, or other control substance) applied to a particular subject. Appropriate statistical tests must be applied to the data to assure that interpretations of efficacy of the test drugs are valid.

Id.

The three other members of the review committee, Drs. Miller, Meyerhoff, and Goode, all submitted affidavits saying that they were aware of Bluestone's industry funding. Dr. Miller, for example, stated that "I was fully aware that

Dr. Bluestone was receiving very substantial support from private pharmaceutical companies to do drug efficacy studies. . . . I was not at all troubled by the fact that Dr. Bluestone was receiving such funding." App. 1104-05.

None of the three, however, informed Drs. Perkell or Schwartz of this outside funding. Dr. Schwartz's affidavit notes that the other committee members did not mention Bluestone's undisclosed funding at the review committee meetings, nor did they "raise the issue of possible conflicts of interest or of the adequacy of safeguards to control against bias in the interpretation of study results . . ." App. at 1125.

II

We have jurisdiction pursuant to 28 U.S.C. § 1291, and we exercise plenary review of a district court's grant of summary judgment. *Barnes v. American Tobacco Co.*, 161 F.3d 127, 138 (3d Cir. 1998). On a motion for summary judgment, a court must determine whether the evidence shows that "there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). Factual disputes invoked to resist summary Judgment must be both material in the sense of bearing on an essential element of the plaintiff's claim and genuine in the sense that a reasonable jury could find in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-251, 106 S.Ct. 2505, 2510-12 (1986). A court should not prevent a case from being presented to the jury simply because the court favors one of several reasonable views of the evidence, for "the judge's function is not himself to weigh the evidence and determine the truth of the matter

but to determine whether there is a genuine issue for trial." *Anderson,* 477 U.S. at 249, 106 S.Ct. at 2511.

III

We begin with the threshold issue of which grant applications can be subject to a *qui tam* suit. Prior to the 1986 amendments to the False Claims Act, a private party was barred from bringing a *qui tam* suit if the action was "based on evidence or information the Government had when the action was brought." 31 U.S.C. § 3730(b)(4) (1982 ed.). The government itself, of course, could still bring suit for such a violation; only private parties were barred from seeking recovery. The implicit logic of the pre-1986 law was that if the government had the relevant information before the plaintiff initiated suit, then the government must be aware of the false claims and didn't need the assistance of private parties to ferret them out. And if the government knew about the information yet did nothing, then the government probably thought the suit meritless, and any private action was apt to be spurious, driven only by the lure of the Act's sizable damages.

Despite the pre-1986 law's legitimate aim of preventing spurious suits, its bar for *qui tam* suits imperfectly achieved its purposes for a variety of reasons: 1) the government lacks the resources to investigate and prosecute all false claims even when the government has information revealing fraud; 2) a government official who is deemed to "have" the information may not recognize the connection between the information and a particular false claim; 3) the official may have an interest in not bringing the fraud to light for a number of reasons, such as an interest in protecting the

official's or the agency's reputation; and 4) other mechanisms, more directly focused on the merits of a suit, are available for filtering out spurious claims. Congress was also concerned that under the old law, whistleblowers who came forward and exposed fraud to government officials before filing suit were later being barred from bringing a *qui tam* suit. Indeed, as our discussion below makes clear, Cantekin's case itself illustrates this consequence of the pre-1986 law.

With the enactment of the Grassley Amendments, Congress generally gave greater scope to *qui tam* suits. Among other changes, such as increasing the damages from double to treble the harm caused, and increasing the percentage that a *qui tarn* plaintiff received of those damages, *compare* 31 U.S.C. §§ 3730(a) and (c) (1982 ed.) *with* 31 U.S.C. §§3730(d)(1) and (2), the amendments also eliminated the old law's bar to *qui tam* suits.

Instead of prohibiting all *qui tam* suits that are based on information the government "has" when the suit is brought, the Grassley Amendments introduced a new standard: a *qui tam* suit will be barred only if it is based on information that was "publicly disclosed" at various hearings, in certain types of reports, or by the media. 31 U.S.C. §3730(e)(4)(A). Information that the government "has," but that was never publicly disclosed, does not bar a *qui tam* suit, Even if there is "public disclosure" within the meaning of the Grassley Amendments, a *qui tam* suit can still go forward if the plaintiff is an original source of that publicly disclosed information. 31 U.S.C. § 3730(e)(4)(B). An original source is defined as someone who has "direct and independent knowledge" of the information and who has "voluntarily

provided" the government with the information before the suit was initiated. *Id.*

Groundless suits are addressed in part by provisions requiring that all *qui tam* plaintiffs submit sealed information to the government before the suit proceeds. After reviewing this information, the government can decide whether to join the suit, allow the private party to continue alone, or, most significantly, dismiss the suit. *See* 31 U.S.C. §§ 3730(b)(2) and (c)(2)(A).

In *Hughes Aircraft Co. v. United States ex rel. Schumer,* 520 U.S. 939, 117 S.Ct. 1871 (1997), the Supreme Court held that the 1986 amendments did not apply retroactively to conduct occurring prior to the amendment's effective date. The Court stated in a footnote, however, that since in *Hughes* both the "false claim submission" and the "disclosure to the government" of the fraud occurred before the effective date of the 1986 amendments, the Court did not have to address which of the two events should be used for determining retroactivity. 520 U.S. at 946, n. 4, 117 S.Ct. at 1876, n.4.

In applying Hughes, the District Court concluded that for all of Bluestone's grant applications submitted prior to the 1986 effective date, the date of "disclosure to the government" also occurred before October 27, 1986. Thus, the District Court decided that, as in *Hughes,* it did not have to resolve whether the disclosure date or the date of submission controls.

Although the parties sharply dispute whether there was "disclosure to the government" prior to the 1986 effective

date, we need not resolve the issue. We conclude that even though the Supreme Court did not expressly reach in *Hughes* whether retroactivity is determined based on the submission date or the disclosure date, the Court's analysis strongly supports using the former, i.e., the date the allegedly false claim was submitted. And once we use the submission date and apply the pre-1986 law to all grant applications submitted prior to the October 27, 1986 effective date, there can be no doubt that before Cantekin began his *qui tam* suit, the government "had" the information upon which it was based.

By the time Cantekin filed his complaint in the District Court on April 29, 1991, the House had conducted its hearings and issued its report, and the NIH had issued both Hyatt's memo and the later report by the Office of Scientific Integrity. These events unquestionably establish that the government had the information on which Cantekin's suit was based.[2] Thus, the only live issue is why we should use the submission date for determining retroactivity.

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[2] Cantekin objects that when the District Court granted summary judgment against his pre-1986 claims, the Court erred by converting a 12(b)(6) motion into a motion for summary judgment without first giving adequate notice and an opportunity to respond. *See, e.g., Rose v. Bartle*, 871 F.2d 331, 342 (3d Cir. 1989). Cantekin raised this point in a motion for reconsideration, but the District Court rejected the argument, noting that under Rose a failure to give notice can be excused if "harmless." *Id.* Since we evaluate retroactivity based on the submission date, and since it is undisputed that Cantekin's suit was fled after the NIH and Congressional investigations, we conclude that any error stemming from the conversion of the motion was indeed harmless.

When the Supreme Court concluded in Hughes that the Grassley Amendments should not be applied retroactively, the Court recognized that knowingly submitting a false claim is illegal under both versions of the statute. The Court also noted that under both the amended statute and the previous statute, the total amount of a defendant's liability does not depend on who sued; the defendant must pay the same amount regardless of whether the government or a *qui tam* relator brought the action. Nonetheless, the Supreme Court reasoned that the amendment's change in when *qui tam* suits can be brought does impose new penalties on defendants.

> While we acknowledge that the monetary liability faced by an FCA defendant is the same whether the action is brought by the Government or by a qui tam relator, the 1986 amendment eliminates a defense to a qui tam suit -- prior disclosure to the Government -- and therefore changes the substance of the existing cause of action for qui tam defendants by "attach[ing] a new disability, in respect to transactions or considerations already past."

520 U.S, at 948, 117 S.Ct. at 1877 (citations omitted). After noting that the 1986 amendments eliminate a defense, the Court commented that the amendments also in effect create a new cause of action because the courts are open to an expanded class of plaintiffs.

We think this reasoning would be in deep tension, if not outright conflict, with using the date of disclosure instead of the date of submission for determining retroactivity. Our primary rationale is very simple. If we invoked the disclosure

date to apply the amendments to a false claim submitted before the amendment's effective date, then the new penalties listed by the Court, i.e., the loss of a defense and the creation of a new cause of action, would be imposed after the defendant acted. The reason that using the disclosure date would have this effect is that the defendant's conduct ends with submitting the false claims; the defendant is not the one, or at least not usually, who makes the disclosure to the government. Since the Court rejected in *Hughes* an application of the Grassley Amendments that would allow the law to "attach new disabilities" to conduct committed prior to the amendment's passage, we think the Court implicitly foreclosed using the disclosure date.

Another problem with using the date of "disclosure to the government" to determine retroactivity is that it is not clear what test should be applied to determine that date. The Supreme Court's phrase "disclosure to the government," straddles the 1986 amendment's "public disclosure" language and the pre-1986 standard of "information the government had." By speaking of disclosure "to" the government, rather than disclosure "by" the government, the Supreme Court's language may suggest that the Court was referring to the pre-1986 "government knowledge" test. The "government knowledge" test is primarily focused on what *other people* release to the government while the amendment's "public disclosure" test has a substantial emphasis on information released *by government*. On the other hand, the Supreme Court's phrase, "disclosure to the government," does not accurately capture the pre-1986 law since the government could "have" the information within the meaning of the pre-1986 test based on what the government learned from its own investigative efforts. And by speaking of "disclosure," and

not information the government "has," the Supreme Court's language is suggestive of the "public disclosure" test.

Regardless of how one parses the language, however, the real problem is that choosing between the pre- and post-1986 standards injects a kind of circularity into the retroactivity analysis. To determine the date of "disclosure to the government," we must apply either the pre- or post-1986 test in order to decide whether we will apply the pre-or post-1986 test to the alleged false claim. This awkward need to stipulate at the outset what our analysis is supposed to decide reinforces our conclusion that the date the claim was submitted should determine the retroactivity of the Grassley Amendments.[3]

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[3] It is true that a court could apply pre-1986 law to assign a date to the "disclosure to the government" and yet still find that post-1986 law should ultimately control the claim. For example, suppose that after the defendant submitted a false claim in 1985, the plaintiff informed the government of the fraud in 1987, filed a *qui tam* suit in 1988, and qualified as an original source. Even if we applied the pre-1986 law to date "disclosure to the government," we would not bar the plaintiff's suit. This follows because the date that the government learned of the fraud, i.e., sometime in 1987, was after the effective date of the 1986 amendments. And once we applied the amended law, we would see that the plaintiff could go forward with the suit since the plaintiff is an original source, and no public disclosure occurred aside from the plaintiff's suit.

The circularity of our presupposing pre-1986 law isn't really eliminated, however, just because in a certain class of cases using the pre-1986 law to assign a date to disclosure leads us to apply post-1986 law. We still need a justification for applying the

The District Court noted in passing that a Ninth Circuit opinion, decided before the Supreme Court's opinion in *Hughes,* relied on the disclosure date for determining the retroactivity of the Grassley Amendments. *See United States ex rel. Anderson v. Northern Telecom., Inc.*, 52 F.3d 810, 814 (9th Cir. 1995). The main problem with *Anderson* is that its reasoning rested heavily on the point that "the 1986 amendment did not change the legal consequences of [defendant] Northern Telecom's conduct." 52 F.3d at 814. Since *Hughes* rejected that position and emphasized that the Grassley Amendments do "attach new disabilities" to a defendant's past conduct, we think that *Anderson's* authority has been undermined. In short, we conclude that we should use the date the claim was submitted for determining the retroactivity of the Grassley Amendment's "public disclosure" bar to *qui tam* suits.

Did Bluestone knowingly submit false claims?

Not all of Cantekin's claims were based on grant applications submitted prior to October 27, 1986. On January 28, 1987, Bluestone submitted a new grant application without listing his industry funding, and he again failed to disclose when he revised the application on May 1, 1987.

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pre-1986 law at the outset when it may foreclose many claims that the post-1986 disclosure test would not. We could, of course, appeal to the considerations cited in *Hughes* for using the pre-1986 law. But once we adopt those arguments, we have reason to abandon the "date of disclosure" altogether as a way of determining retroactivity.

The District Court dismissed Cantekin's *qui tam* claim based on this revised application because the Court concluded on summary judgment that the evidence "does not permit a finding that Dr. Bluestone 'knowingly' submitted false or fraudulent claims to the government." App. at 1627.

The False Claims Act defines "knowing" and "knowingly" as including a defendant's "actual knowledge," "deliberate ignorance," or "reckless disregard" of the truth or falsity of information in the defendant's claim to the government. 31 U.S.C. § 3729(b). The statute adds that "no proof of specffic intent to defraud is required." *Id.* In applying these standards to the record before us, we must heed the basic rule that a defendant's state of mind typically should not be decided on summary judgment. *See, e.g., Hunt v. Cromartie*, __ U.S. , 119 S.Ct. 1545, 1552 (1999).

The District Court's primary rationale for granting summary judgment was that the grant application and instructions were unclear. Before we address whether the instructions are ambiguous, or more properly whether there is no genuine dispute that they are, we note that Cantekin stated in his affidavit that he specffically informed Bluestone that he should disclose his private funding.

> In 1976, when Dr. Bluestone and I were applying for various NIH grants, I raised with Dr. Bluestone the question whether he, as principal investigator, should not be disclosing to NIH his other research support, especially from pharmaceutical companies. Dr. Bluestone replied that it was "none of their business," and that he was not going to tell the

> "federal feather merchants" because it would "muddy up the waters." Dr. Bluestone added that "idiots like Buckminster Ranney would not understand." Dr. Buckminster Ranney was an NIH-employee working with the National Institute of Neurological, Communicative Disorders, and Stroke ("NINCDS") with whom Dr. Bluestone had dealt.

App. at 523. This affidavit not only creates a genuine dispute that Bluestone "knowingly" omitted his industry funding, but it also provides evidence that Bluestone had the specific intent to defraud, proof of which is not required for a violation of the False Claims Act.

Even apart from the evidence that Bluestone was specifically informed that he should disclose his industry funding, we conclude that there is ample evidence that the instructions are clear. Other members of Bluestone's Otitis Media Research Center correctly followed the instructions and disclosed their outside research funding, including private sources. App. at 38. Similarly, one of the NIH review committee members, Schwartz, stated in his affidavit that:

> I have written or helped to write numerous NIH grant applications for fellowships, research grants, program projects and training grants. As principal investigator I have held an R01 grant from NIH which has been continuously funded since 1972 involving seven competing renewals and several revised resubmissions . . . I have always found

> directions for completing the "other support" pages of NIH grant applications to be unambiguous.

App. at 439-40. Another member of the review committee, Perkell, submitted a similar affidavit saying that he had applied for and received a number of NIH grants and found the "other support" section to be unambiguous.

A review of the instructions themselves suggests that they clearly indicate that industry funding should be disclosed. On the page that instructs applicants to list their "other support," the form provides:

> For each of the professionals named on page 2, list, in three separate groups: (1) active support; (2) applications pending review and/or funding; (3) applications planned or being prepared for submission. Include *all* Federal, non-Federal, and institutional grant and contract support. If none, state "NONE." For each item give the source of support, identifying number, project title, name of principal investigator / program director, time or percent of effort on the project by professional named, annual direct costs, and entire period of support. (If part of a larger project, provide the titles of both the parent grant and the subproject and give the annual direct costs for each.) Briefly describe the contents of each item listed. If any of these overlap, duplicate, or are being replaced or supplemented by the present application,

> justify and delineate the nature and extent of the scientific and budgetary overlaps and boundaries.

App. at 1196 (emphasis in original). The instructions specifically request that the applicant list "all . . . non-Federal. . . support" and give detailed information about each grant.

In concluding that the instructions were ambiguous, the District Court relied on Hyatt's report, which cited an earlier version of the instructions and said that "many institutions were found to interpret those instructions improperly." App. at 509. Hyatt explained that the NIH changed the instructions to avoid ambiguities.

The District Court's reliance on Hyatt's memo is problematic for a number of reasons. First, Bluestone's post-1986 grant applications *used the improved instructions.* Second, even if potential confusion from the earlier applications was relevant, perhaps because the earlier instructions gave Bluestone erroneous expectations, we seriously question whether the earlier instructions were ambiguous. The instructions that Hyatt claimed were ambiguous read in part:

> List all research support for each individual including requests now being considered, as well as any proposals being planned, regardless of relevance to this application. Include also current awards, research career program awards, training grants, regardless of the source of support.

App. at 509. Hyatt apparently believed that these instructions were ambiguous because, unlike the improved instructions, they did not specifically refer to "non-Federal" sources. The instructions did, however, direct applicants to list "all" research support "regardless of source" and "regardless of relevance." Hyatt claimed that "many" institutions had incorrectly interpreted the earlier instructions, but the drafter of the NIH forms testified that he could not recall any specific case, except Bluestone's of course, where a researcher misunderstood what was required by the "other support" question.

Third, the House report sharply criticized Hyatt's conclusions and explained that:

> NIH officials were incorrect in describing the content of the NIH forms; the section regarding "Other Support" was revised in late 1979 and revised forms, containing the more explicit language were available to applicants in 1980 or 1981, depending on the type of application.

App. at 38,

Fourth. Dr. Hadley, the Acting Deputy Director of the NIH's Office of Scientific Integrity, asserted in her affidavit that she had not encountered any evidence that applicants found the instructions to be ambiguous.

> In my opinion and based on my [prior] experience as an Executive Secretary [who works with review committees in evaluating

> grant applications,]. . . there was never any problem with ambiguity in PHS instructions on how to complete the "Other Support" section of a PHS Grant Application or Continuation Application. From Fall, 1979 on, the instructions explicitly required the disclosure of all sources of support, both federal and non-federal.

App. at 482.

Finally, one can infer that Bluestone, a highly-educated professional, would have been aware that the NIH might be interested in his industry ties when the agency decided whether to award him substantial funding to test a key drug in a half-billion dollar industry. As Cantekin points out, people are likely to give much greater weight to NIH research than to the findings of companies making the drugs at issue. Given this greater public trust in the results of government-funded research, and the undeniable risks of bias, the government clearly has a strong interest in ensuring that it acts as an impartial investigator, especially when investigating treatments that have a disputed efficacy and a high aggregate cost. Bluestone can be reasonably expected to know of the government's heightened interest in avoiding bias. As a scientist, he must be fully aware that rooting out potential sources of bias in our interpretations of empirical data is central to scientific inquiry.

The District Court and the appellees' next argument is that in the materials accompanying some of Bluestone's applications, there were references to his industry funding. These references were by no means complete disclosures of

the grants he was receiving from pharmaceutical companies, nor did the references include the full information, such as the amount of the funding, that was requested in the "Other Support" section of the grant application. Furthermore, many of the references that the appellees rely upon were included with "progress reports," which were submitted after a grant was approved. But the most important point is that scattered references buried in voluminous accompanying materials do not comply with the application's disclosure requirements.

When a reviewer is faced with complex proposals that include large masses of accompanying information, it makes sense to insist that the applicants must disclose in one place the applicant's other grants that may raise conflicts of interests or impose competing demands on the applicant's time. A reviewer who is reading an applicant's accompanying journal article may not notice, while engrossed in the details of a specialized scientific issue, a fleeting reference to private funding and think of its significance for potential conflicts of interest. Applications distill and organize information for a reason.

Evidence in the record bears out this point. One of the review committee members, Perkell, stated in his affidavit that:

> As a grant reviewer and evaluator I have always looked to the "Other Support" pages to form an estimate of the percentage of effort the Principal Investigator and other investigators have available to do the proposed work, to look for possible overlap between proposed projects and others already funded or pending,

> and to identify possible conflicts of interest or possible sources of bias in the experiments. These factors are important to me in evaluating an application as a whole and in assigning it a priority score.

App. at 472. Schwartz, another review committee member, likewise stated in her affidavit that she relies on the "Other Support" section to gauge how much time the applicant has to spend on the research, whether the proposal is duplicative, and what conflicts of interest the applicant might have. Despite the references Bluestone cites in the accompanying materials, neither Schwartz nor Perkell was aware of Bluestone's industry funding, and both said it would have affected their evaluation of his application.

The District Court's last reason for concluding that Bluestone did not knowingly submit a false claim is that he sent a letter on June 23, 1987 to Elkins, his program administrator, listing his industry funding. We find the District Court's reliance on this letter unconvincing. Not only was it written months after Bluestone submitted his application in January and May of 1987, but more important, the letter was only sent after he was under investigation. Given that Bluestone only sent the letter after Cantekin made his allegations to the NIH and the university, the timing of the letter tends to-reinforce, not undermine, Cantekin's allegations that Bluestone knew that he was supposed to disclose his industry funding. One can easfiy infer that the letter was not an expression of an honest oversight, but an attempt to cover up prior misconduct and limit its damage.

Cantekin alleges that program administrators' interests are more closely allied with grant applicants' than any other NIH official, so it is noteworthy that Bluestone chose to notify Elkins, and Elkins alone, at the NIH. Reading the evidence in the light most favorable to the nonmoving party, if Bluestone calculated that disclosure to Elkins would be the least damaging step he could take, his judgment apparently proved correct since the letter he sent to Elkins was never forwarded beyond the program-administration offices.

Another problem with relying on Bluestone's letter to Elkins as a way of exonerating him for submitting a false claim is that the False Claims Act has a specific provision dealing with someone who comes forward and discloses his or her false claims. The statute provides that

> [I]f the court finds that --
>
> (A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;
>
> (B) such person fully cooperated with any Government investigation of such violation; and
>
> (C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action,

> or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation;
>
> the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of the person. A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

31 U.S.C. § 3729(a)(7).

The first point worth noting is that this provision merely *reduces* the defendant's liability from treble to double damages; it does not exonerate a defendant for a violation. Second, Bluestone's letter of June 23 was more than 30 days after the date he made his false statements. Third, Bluestone's letter was sent after he was under investigation, and thus he arguably cannot satisfy subsection (C). It also may be open to dispute whether he has "fully cooperated" or provided "all information" that he knew about the violation.

Taking up a different issue, the District Court cited *United States ex rel. Hopper v. Anton,* 91 F.3d 1261, 1266-67 (9th Cir. 1996) for the proposition that a "technical violation of rules and regulations of an agency is not actionable under the FCA." App. at 1627. What the Ninth Circuit held in *Hopper,* however, was that not every regulatory violation is tantamount to making a knowingly false statement to the

government. Since the regulatory violation in *Hopper* did not involve making a knowingly false statement in a claim submitted to the government, the court held there was no violation of the False Claims Act. Thus, *Hopper* does not stand for the proposition that before a court allows a suit to proceed under the False Claims Act, it must weigh how serious it thinks a particular knowing falsehood was in a claim submitted to the government.

Although we reject the District Court's reading of *Hopper,* the Court's remark about "technical violations" suggests two slightly different objections: Bluestone's omissions were not material, and even if they were, they did not cause any damages to the government. We will consider first the materiality objection.

Courts have held that claims under the False Claims Act are subject to a judicially imposed materiality requirement. *See, e.g., Harrison v. Westinghouse Savannah River Co.,* 176 F.3d 776, 784 (4th Cir. 1999). And the Supreme Court recently held in *Neder v. United States,* __U.S.__, 119 S.Ct. 1827 (1999) that there is a materiality requirement under the federal mail-fraud, wire-fraud, and bank-fraud statutes. In a footnote, the Supreme Court indicated, however, that the term "false statement," unlike "fraudulent statement," does not imply a materiality requirement. *Neder,* 119 S.Ct, at 1840 n.7. Given that the False Claims Act prohibits merely making a knowingly false claim and does not require a specific intent to defraud, perhaps *Neder* argues against a materiality requirement. In any event, we need not decide whether there is a materiality requirement under the False Claims Act, because even if there is, we think it is clear that Bluestone's failure to disclose his

industry funding would readily qualify as material. In *Neder*, the Supreme Court quoted from the Restatement (Second) of Torts, which provides two alternatives for showing that a matter is material:

> (a) a reasonable man would attach importance to its existence or nonexistence in determining his choice of action in the transaction in question: or
>
> (b) the maker of the representation knows or has reason to know that its recipient regards or is likely to regard the matter as important in determining his choice of action, although a reasonable man would not so regard it.

Neder, 119 S.Ct. at 1840 n.5 (*quoting* Restatement (Second) of Torts § 538 {1976)).

As recounted above, industry funding is relevant for assessing conflicts of interest, how much time an applicant has to devote to the requested NIH grant, and how the research fits within a broader research program. Because the NIH specifically requests the information on its form, and because the value of this information is readily apparent, we think that the information is material: a reasonable NIH grant applicant would know that the NIH regards the information as important.

We turn now to the issue of damages. Even if the letter to Elkins does little to undermine Cantekin's claim that Bluestone knowingly submit false claims, the appellees argue that the letter still shows that his earlier failure to disclose

caused no harm. Bluestone sent the letter to Elkins on June 23, 1987, but his pending post-1986 application was not finally approved until February 4, 1988, when he was awarded $321,137. The appellees argue, therefore, that no harm could have been caused because Bluestone disclosed his industry funding before any grant money was dispensed for his post-1986 grant application.

The first problem with this argument is that, as noted above, the letter to Elkins never left the program-administration offices, so the information about Bluestone's industry funding never reached the review committee or any other decisionmaker involved in approving Bluestone's grant. Thus, we do not know whether the review committee or the council of the institute would have approved the grant if they had known about the information included in the letter. Given that two committee members who reviewed Bluestone's application in 1984 and 1985 would have assigned lower priority scores to his application, and given that one member's vote can effectively deny funding, we think whether the grant would have been approved and what damages were incurred raise genuine factual disputes. We also want to point out that even if the review committee and council would have approved the application once they knew about the industry funding, they still might have imposed additional safeguards or requirements. Having not been informed, they did not have an opportunity to consider these other intermediate steps.

It may seem unfair to hold Bluestone accountable for the decision made in the program-administration offices not to pass along Bluestone's letter. As noted above, however, the statute expressly provides a mechanism for dealing with a defendant who reveals his false claim. Since this provision

merely reduces the defendant's liability for the damages actually caused, and since, in any event, Bluestone may not satisfy the prerequisites, Bluestone remains liable for the harm that in fact was caused to the government as a result of his false statements.

It is a basic principle of tort law that once a defendant sets in motion a tort, the defendant is generally liable for the damages ultimately caused, unless there are intervening causes. *See*, *e.g.*, W. Keeton, D. Dobbs, R. Keeton, & D. Owen, Prosser and Keeton on Law of Torts § 44 (5th ed. 1984). Analysis of intervening causes is often used as a way of evaluating and assigning responsibility for harm caused. *Id.* Given that Bluestone only sent his letter after he was under the pressure of investigation, his letter does little to lessen his culpability, and therefore, the fact that the letter was not forwarded is not plausibly treated as an intervening cause. To the extent that analysis of intervening causes focuses on the foreseeability of a putative intervening cause, we think it is significant that Bluestone chose to send the letter to Elkins, his program administrator, who did not decide whether he would receive funding for his application. Bluestone did not, for instance, submit another revised application as he did earlier in the spring. In short, the fact that the letter was not forwarded was a risk that Bluestone assumed when he submitted the claims.

The appellees have directed our attention to several cases discussing causation requirements under the False Claims Act. In *United States v. First Nat'l Bank of Cicero,* 957 F.2d 1362 (7th Cir. 1992) the court held that the government only needed to show that it would not have made a payment "but for" the false statement. In reaching that

holding, the Seventh Circuit expressly disagreed with *United States v. Hibbs,* 568 F.2d 347 (3d Cir. 1977), which, according to *Cicero*, imposed a more stringent causation requirement. Specifically, *Cicero* said that in addition to requiring that the government would not have paid the claim but for the false statement, *Hibbs* effectively held that the "subject matter of the false statement . . . be the source of the government's loss." 957 F.2d at 1373 (*citing Hibbs,* 568 F.2d at 349, 351). We need not decide either whether *Hibbs* should be read as imposing such a requirement, or whether *Hibbs* is consistent with the changes made in the False Claims Act since that decision. We think it suffices to point out that both standards can be satisfied; as we concluded in our discussion of damages, Cantekin has presented evidence that Bluestone's grant might not have been approved but for his false statements about his industry funding (or that the grant would have been approved with additional restrictions or requirements). And the content of Bluestone's omissions about his industry funding could have made the difference in whether his grant was approved or not, so even under the Seventh Circuits reading of *Hibbs*, the "subject matter of the false statement" could have been the source of the government's loss.

IV

For the foregoing reasons, we will affirm the order of the District Court dated February 9, 1998 and reverse the order dated September 4. 1998. Each party to bear its own costs.

STAPLETON, Circuit Judge, *concurring:*

Because, in my view, (1) the uncontradicted evidence establishes that responsible government employees knew of the private funding and alleged conflict of interest prior to the effective date of the Grassley Amendments; (2) the instructions to applicants are clear and unambiguous on their face; and (3) Dr. Cantekin's affidavit alone establishes a dispute of fact as to whether Dr. Bluestone knowingly submitted false claims, I join the judgment of the Court.

A True Copy:

Teste:

Clerk of the United States Court of Appeals
for the Third Circuit

APPENDIX B

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

[Filed September 29, 1999]

No. 98-3552

UNITED STATES OF AMERICA, ex rel. ERDEM I. CANTEKIN, an individual

v.

UNIVERSITY OF PITTSBURGH, a non-profit Pennsylvania corporation; CHILDREN'S HOSPITAL OF PITTSBURGH, a non-profit Pennsylvania corporation; CHARLES D. BLUESTONE, an individual;

United States of America, ex rel. Erdem I. Cantekin,
Appellant

(Amended pursuant to Clerk's order dated 1/7/99)

On Appeal From the United States District Court
For the Westem District of Pennsylvania

(D.C. Civ. No. 91-cv-00715)
District Judge: Honorable Donald E. Ziegler, Chief Judge

Present: NYGAARD, STAPLETON AND COWEN, Circuit Judges

JUDGMENT

This cause came on to be heard on the record from the United States District Court for the Western District of Pennsylvania and was argued by counsel on June 17, 1999.

On consideration whereof, it is now here ordered and adjudged by this Court that the judgment of the said District Court entered February 9, 1998, be, and the same is hereby affirmed, and that the judgment of the said District Court dated September 4, 1998 and entered September 9, 1998, be, and the same is hereby reversed. Each party to bear its own costs. All of the above in accordance with the opinion of this Court.

ATTEST:

/s/_____
Clerk

Dated: September 29, 1999

Certified as a true copy and issued in lieu
of a formal mandate on May 30, 2000

Teste: /s/_____
Acting Clerk, United States Court of
Appeals for the Third Circuit

APPENDIX C

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

[Filed October 5, 1998]

No. 95-552

ERDEM I. CANTEKIN,
Plaintiff,
v.

THE UNIVERSITY OF PITTSBURGH, CHARLES D. BLUESTONE, EUGENE N. MYERS and THOMAS P. DETRE
Defendants.

ORDER OF COURT

AND NOW, this 5th day of October, 1998,

IT IS ORDERED that from this date forward all documents which pertain only to civil action 95-552 shall be filed at the above captioned case number.

/s/
Donald E. Ziegler
Chief Judge

cc: Counsel of record

APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

[Filed October 2, 1998]

No. 91-0715

UNITED STATES OF AMERICA ex rel. ERDEM I. CANTEKIN, *Plaintiff*,

v.

UNIVERSITY OF PITTSBURGH, a non-profit Pennsylvania corporation; CHILDREN'S HOSPITAL OF PITTSBURGH, a non-profit Pennsylvania corporation; and CHARLES D. BLUESTONE, an individual, *Defendants*.

ORDER

In April 1991, Erdem I. Cantekin, Ph.D., as Relator, filed a *Qui Tam* action on behalf of the United States under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, against the University of Pittsburgh, Children's Hospital of Pittsburgh

and Charles D. Bluestone, M.D. This *Qui Tam* case was docketed by the Clerk of this Court at Civil Action No. 91-0715. In the *Qui Tam* case, Dr. Cantekin sought to recover on behalf of the United States certain research funding which had been provided by the National Institutes of Health (the "Research Funding").

In March 1995, Dr. Cantekin filed a civil action in the Court of Common Pleas of Allegheny County, Pennsylvania against the University of Pittsburgh. The University removed that case to this Court and the Clerk docketed this second suit at Civil Action No. 95-552. An Amended Complaint in No. 95-552 was filed in or about September 1995 adding three individuals (Charles D. Bluestone, Eugene N. Myers and Thomas P. Detre) as Defendants.

The Amended Complaint in the second civil action, No. 95-552, asserted, *inter alia,* claims that Dr. Cantekin had suffered alleged retaliation in violation of the False Claims Act's "whistleblower" provision, 31 U.S.C. 3730(h), as a result of his having sought to assert the alleged rights of the United States to recover the Research Funding. This Court, *sua sponte,* on May 30, 1995 ordered the two civil actions consolidated at the earlier docket number, Civil Action No. 91-0715.

On August 25, 1997, this Court entered an Order which granted "partial summary judgment" on the claims asserted in the *Qui Tam* case for alleged violations which allegedly occurred prior to October 27, 1986.

On September 4, 1998, this Court entered a further Order which granted "partial summary judgment" on the

claims asserted in the *Qui Tam* case for alleged violations which allegedly occurred after October 27, 1986.

This Court is of the opinion that the two "partial" summary judgment orders entered in the *Qui Tam* case, when taken together, constitute a determination that there are no claims remaining in the *Qui Tam* case (civil Action No. 91-0715). This Court has consulted with counsel for all parties to the *Qui Tam* case and counsel concur with this opinion. This Court is of the opinion, therefore, that a "Final Judgment" or "Final Order" should now explicitly be entered in the *Qui Tam* case. Given that a "Final Judgment" should be entered in the *Qui Tam* case, there is no further reason to view the "whistleblower" case, filed in 1995, as "consolidated" with the *Qui Tam* case.

The order of May 30, 1995 which consolidated the two civil actions, No. 91-0715 and No. 95-552, is hereby VACATED. The Clerk is directed to remove from the original file of No. 91-0715 all documents which pertain only to the "whistleblower" case, No. 95-552, and to transfer those documents to a separate file at No. 95-552. The original file of this Court at No. 91-0715 should contain only documents pertaining to the *Qui Tam* case. Counsel for the parties at No. 95-552 will assist the Clerk, as necessary, in identifying documents which pertain to No. 95-552 and which should be removed from the original file at No. 91-0715.

The Clerk is further directed to enter FINAL JUDGMENT in favor of all Defendants and against the United States at No. 91-0715 and to mark that case "closed." The entry of FINAL JUDGMENT by the Clerk pursuant to this order will be the final order entered at No. 91-0715. The

entry of Final Judgment pursuant to this paragraph by the Clerk shall not affect and shall not pertain to Civil Action No. 95-552, the "whistleblower" case.

/s/_____

Donald E. Ziegler
Chief Judge
October 2, 1998

APPENDIX E

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

[Filed September 4, 1998]

No. 91-0715

UNITED STATES OF AMERICA ex rel. ERDEM I. CANTEKIN, *Plaintiff*,

v.

UNIVERSITY OF PITTSBURGH, a non-profit Pennsylvania corporation; CHILDREN'S HOSPITAL OF PITTSBURGH, a non-profit Pennsylvania corporation; and CHARLES D. BLUESTONE, an individual, *Defendants*.

OPINION

ZIEGLER, Chief Judge.

Pending before the court is the motion of defendants for summary judgment pursuant to Rule 56(c) of the Federal Rules of Civil Procedure. Previously, the court granted

defendants' motion for summary judgment with respect to the alleged Federal Claims Act violations predating October 27, 1986. Defendants now challenge the alleged violations of the Act which occurred after October 27, 1986. Specifically, defendants argue that plaintiff is unable to sustain his burden of presenting sufficient evidence on the question whether Dr. Bluestone intended to defraud the government. Defendants further contend that the knowledge by governmental officials of Dr. Bluestone's private funding, prior to approval of the supplemental grant application, negates Dr. Cantekin's claim. We turn to these arguments.

FACTS

During January 1987, Dr. Charles Bluestone submitted two applications to the National Institute of Neurological and Communications Disorders and Stroke ("NINCDS") for funding which did not disclose private funding in the "other support" sections of the applications. The government declined to award funds for the first supplemental application.[1] The second supplemental grant application, NS16337-08S2, which was to support clinical trials, was ultimately funded in February 1988. However, prior to funding, Dr. Bluestone revised the second application and submitted the revised version to NINCDS on or about May 1,

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[1] According to defendants, the government subsequently reviewed and approved a revised version of this application, NS16337-08SA1, which was submitted on September 28, 1987, and which disclosed Dr. Bluestone's private funding in the other support section. Reply Mem. in Supp. of Def.s' Mot. for Summ. J. at 2.

1987. The revised supplemental application did not list Dr. Bluestone's private funding in the "other support" section.

On or about May 1, 1987, Dr. Cantekin submitted a letter to the National Institutes of Health ("NIH") alleging that Dr. Bluestone had consistently failed to disclose private funding in the PHS 398 Grant Applications and the PHS 2590 Application for Continuation Grants. In response to Cantekin's allegations, Bluestone submitted a letter to Dr. Earleen Elkins on or about June 23, 1987, wherein he refuted Dr. Cantekin's allegations, and further listed and detailed the private funding. On or about February 4, 1988, the NINCDS issued a Notice of Grant Award for the revised supplemental grant application.

ANALYSIS

As the basis for his qui tam action under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, Dr. Cantekin alleges that Dr. Bluestone made false statements to NIH in revised supplemental grant application NS16337-08S2. Specifically, Cantekin alleges that Bluestone's failure to list his private support in the "other support" section of the application constitutes a fraud or fraudulent statement to the government.

Section 3729(a)(1) of the act imposes liability for any person who "knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval." 31 U.S.C. §3729(a)(1). To establish knowing presentation of a false claim under the FCA, a plaintiff must show that (1) the defendant presented or cause to be presented

to an agent of the United States a claim for payment, (2) the claim was false (3) the defendant knew it was false, and (4) resulting damage. See Id.

The FCA defines "knowing" as having "actual knowledge" of the information, or acting in either deliberate indifference to or "reckless disregard" for the information's truth or falsity. 31 U.S.C. §3729(b). The scienter requirement, which is critical to the operation of the FCA, requires "the knowing presentation of what is known to be false, [i.e.,] . . . a lie." United States ex rel. Hochman v. Nackman, 145 F.3d 1069, 1073 (9th Cir. 1998).

Defendants contend that summary judgment is appropriate because Dr. Bluestone lacked the requisite intent. Specifically, defendants note that, although not included in the "other support" section of the application, Dr. Bluestone disclosed the private funding in other sections of the applications and the government knew of such funding. Further, defendants argue that Bluestone's letter of June 23, 1987 to the NINCDS further disclosed the private funding almost six months prior to the Notice of Grant Award for NS16337-08S2.

Dr. Cantekin rejoins that summary judgment should be denied because Bluestone "did not list his private funding in the 'other support' section." Pl.'s Br. in Opp'n to Summ. J. at 41. Plaintiff further contends that the failure to disclose the private funding was material and caused damage, as evidenced by Dr. Joseph Perkell's statement that had he known of Bluestone's private funding, '"[t]he impact on the priority score I gave would have been material and negative." Pl.'s Ex. A at ¶ 8. Thus, according to Cantekin, "[t]he present

motion for summary judgment, therefore, must needs [sic] be based on the theory that there is no 'but for' causation." Pl.'s Br. in Opp'n to Summ. J. at 49.

In our view, the dispositive issue is whether Dr. Bluestone "knowingly" submitted false or fraudulent information to the government. As rehearsed, a party "knowingly" presents false and fraudulent claims to the government under the FCA when he/she acts with deliberate ignorance or with reckless disregard of the truth or falsity of one's false claims. See Wang. v. FMC Corp., 975 F.2d 1412, 1420 (9th Cir. 1992). Innocent mistakes and negligence are insufficient to impose liability under the FCA. See United States ex rel. Hagood v. Sonoma County Water Agency, 929 F.2d 1416, 1421 (9th Cir. 1991). Further, taking advantage of a disputed legal question, or the technical violation of rules and regulations of an agency is not actionable under the FCA. See United States ex rel. Hopper v. Anton, 91 F.3d 1261, 1266-67 (9th Cir. 1996), cert. denied __ U.S. __, 117 S. Ct. 958 (1997).

We hold that the evidence relied upon by plaintiff does not permit a finding that Dr. Bluestone "knowingly" submitted false or fraudulent claims to the government. First, the grant application and instructions were unclear and subject to varying interpretations with respect to what was required in the "other support" section. Indeed, the NIH's Division of Management Survey and Review ("DMSR"), through Acting Director Howard Hyatt, expressly noted that although it did "not feel that the OMRC met the . . . requirements, which were intended to provide NIH information on the level of effort researchers were devoting to various projects so it could make informed decisions related thereto, many other

institutions incorrectly interpreted these same instructions." Reply Mem. in Supp. of Def.s' Mot. for Summ. J. at Ex. A (emphasis added). Further, Hyatt also indicated that "[b]ecause of this [incorrect interpretations], NIH has made several revisions to the instructions in the grant application form; these revisions were made in an attempt to avoid ambiguities." Id. (emphasis added).

More importantly, NIH stated that "we feel that none of the instructions have been clear enough to eliminate multiple interpretations." Id. (emphasis added). Thus, based on DMSR's statements, there was uncertainty among "many other institutions" as to what the instructions required to satisfy the application requirements. It is neither deliberately ignorant nor recklessly disregardful to take advantage of a disputed legal question or varying interpretations in instructions. Summary dispositions have been sustained in such cases. See, e.g., Hochman, 145 F.3d at 1074; Hagood v. Sonoma County Water Agency, 81 F.3d 1465, 1478 (9th Cir.), cert. denied, ___ U.S. ___, 117 S.Ct. 175 (1996); accord United States v. Hughes Helicopters. Inc., 71 F.3d 321, 330 (9th Cir. 1995) (directed verdict properly granted because, inter alia, "improper interpretation . . . of a contract, without more, does not constitute a false claim for payment").

Second, Dr. Bluestone's disclosure in earlier applications and in his June 23, 1987 letter, albeit not in the "other support" section, negates any possible finding that he knowingly submitted a false or fraudulent claim. Plaintiff correctly notes that simply because a defendant has disclosed the underlying facts to the government does not establish the absence of intent to deceive. However, governmental

knowledge of the underlying facts "may show that the defendant did not submit its claim in deliberate ignorance or reckless disregard of the truth." Hagood, 929 F.2d at 1421; see also United States ex rel, Kreindler & Kreindler v. United Techs. Corp., 985 F.2d 1148, 1157 (2d cir.), cert. denied, 508 U.S. 973 (1993).

Here, as noted, the government was aware of Bluestone's private funding prior to submission of the 1987 amended applications. Further, on or about June 23, 1987, and in earlier applications, Dr. Bluestone disclosed, albeit not in the "other support" section, that he was receiving private funding. These facts, when coupled with the ambiguities in the instructions, establish as a matter of law the absence of scienter, under these circumstances.

Where a document and accompanying instructions requesting information are subject to several interpretations, as noted by DMSR, and "many other institutions [as well as defendants] incorrectly interpreted these same instructions[,]" there is no basis to impose liability under the FCA. Dr. Cantekin has shown, at best, that Dr. Bluestone may have been negligent. Negligence, however, cannot form the basis for FCA liability. See Hochman, 145 F.2d at 1074; Wang, 975 F.2d at 1420-21; Hagood, 929 F.2d at 1421.

We have carefully reviewed the evidence and arguments by plaintiff and conclude that there is simply insufficient evidence of record to create a genuine issue of material fact to support plaintiff's claims. Defendants' motion for summary judgment will be granted.

An appropriate order will follow.

/s/_____
Donald E. Ziegler
Chief Judge

cc: Counsel of Record

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

[Filed September 4, 1998]

No. 91-0715

UNITED STATES OF AMERICA ex rel. ERDEM I. CANTEKIN, *Plaintiff*,

v.

UNIVERSITY OF PITTSBURGH, a non-profit Pennsylvania corporation; CHILDREN'S HOSPITAL OF PITTSBURGH, a non-profit Pennsylvania corporation; and CHARLES D. BLUESTONE, an individual, *Defendants*.

ORDER

AND NOW, this 4th of September, 1998, after consideration of the defendants' motion for summary judgment pursuant to Rule 56(c) of the Federal Rules of Civil Procedure, and the written submissions of the parties,

IT IS ORDERED that defendants' motion for summary judgment with respect to the post-October 27, 1986 conduct shall be and hereby is granted.

/s/_____
Donald E. Ziegler
Chief Judge

cc: Counsel of Record

APPENDIX F

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

[Filed February 9, 1998]

No. 91-0715

UNITED STATES OF AMERICA ex rel. ERDEM I. CANTEKIN, *Plaintiff*,

v.

UNIVERSITY OF PITTSBURGH, a non-profit Pennsylvania corporation; CHILDREN'S HOSPITAL OF PITTSBURGH, a non-profit Pennsylvania corporation; and CHARLES D. BLUESTONE, an individual, *Defendants*.

OPINION

Pending before the court is plaintiff's motion for reconsideration pursuant to Federal Rule of Civil Procedure 59(e). Plaintiff, Erdem I. Cantekin ("Cantekin"), filed the instant motion alleging that the court improperly converted the motion of defendants, University of Pittsburgh, Children's

Hospital of Pittsburgh, and Charles D. Bluestone (the "defendants"), to dismiss into a motion for summary judgment without providing notice to the parties. Plaintiff further contends that the post-October 27, 1986 False Claims Act ("FCA") claims are viable even if the court denies the pending motion for reconsideration.

Plaintiff raises several arguments in support of the instant motion. First, plaintiff contends that the court's failure to give notice of the conversion of the 12(b)(6) motion into a motion for summary judgment constituted procedural error. Second, plaintiff contends that the grant of summary judgment was itself improper. Finally, plaintiff argues that even if the court refuses to set aside the motion for summary judgment, plaintiff's post-October 27, 1986 False Claims Act ("FCA") claims should survive. We consider these arguments below.

I. MOTION FOR RECONSIDERATION

A motion styled as a "motion for reconsideration" is the "functional equivalent" of a Rule 59(e). motion. Federal Kemper Ins. Co. v. Rauscher, 807 F.2d 345, 348 (3d Cir. 1986). Rule 59(e) of the Federal Rules of civil Procedure gives a party the right to file a motion to reconsider, provided the motion is timely. In re Sharon Steel Corp., 918 F.2d 434, 436 (3d Cir. 1990). Specifically, Rule 59(e) provides: "[a]ny motion to alter or amend a judgment shall be filed no later than 10 days after entry of the judgment."[1] Fed. R. Civ. P.

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[1] Rule 59(e) requires that a motion to reconsider be made within ten days of the entry of judgment. The court's order granting summary judgment was entered on August 25, 1997. The

59(e). A proper motion to alter or amend a judgment must rely on one of three major grounds: (1) an intervening change in controlling law; (2) the availability of new evidence not previously available; or, (3) the need to correct clear error of law or prevent manifest injustice. North River Ins. Co. v. Cigna Reinsurance Co., 52 F.3d 1194, 1218 (3d Cir. 1995) (citation omitted).

Rule 12(b)(6) allows a defendant to test the sufficiency of a plaintiff's pleadings. Where a defendant raises a 12(b)(6) motion to dismiss for failure to state a claim upon which relief can be granted, and the court considers matters outside the pleading, "the motion shall be treated as one for summary judgment and disposed of as provided in Rule 56, and all parties shall be given reasonable opportunity to present all material made pertinent to such a motion by Rule 56." Fed. R. Civ. P. 12(b). Accord Carter v. Stanton, 405 U.S. 669, 671 (1972).

Plaintiff contends that the court's failure to provide notice of its intent to convert the 12(b)(6) motion into a motion for summary judgment was procedural error. Cantekin further contends that the grant of summary judgment was itself improper. Therefore, plaintiff argues, the court

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motion to reconsider was filed on September 9, 1997, which is 15 days after the August 25 order. However, Rule 6(a) of the Federal Rules of Civil Procedure provides that when "the period of time prescribed or allowed is less than 11 days, intermediate Saturdays and Sundays, and legal holidays shall be excluded in the computation." Excluding Saturdays, Sundays and Labor Day, the motion to reconsider was timely filed.

should vacate the August 25 order granting partial summary judgment.

The Court of Appeals has "held that it is reversible error for a district court to convert a motion under Rule 12(b)(6) or Rule 12(c) into a motion for summary judgment unless the court provides notice of its intention to convert the motion and allows an opportunity to submit materials admissible in a summary judgment proceeding or allows a hearing." Rose v. Bartle, 871 F.2d 331, 342 (3d Cir. 1989). See also Hilfirty v. Shipman, 91 F.3d 573, 578 (3d Cir. 1996) (noting general rule); Castle v. Cohen, 840 F.2d 173, 179-80 (3d Cir. 1988) (vacating summary judgment where district court converted Rule 12(b)(6) motion without notice to the parties); Davis Elliott Int'l, Inc. v. Pan American Container Corp., 705 F.2d 705, 706-08 (3d Cir. 1983) (reversing summary judgment where district court acted without notice to the parties and without an opportunity for hearing); Crown Cent. Petroleum Corp. v. Waldman, 634 F.2d 127, 129 (3d Cir. 1980) (reversing summary judgment where district court acted without notice to the parties and without allowing an opportunity to submit affidavits); Bryson v. Brand Insulations, Inc., 621 F.2d 556, 559 (3d Cir. 1980) (same).

"The failure to give adequate notice does not, however, require automatic reversal; it may be excused if the failure was a 'harmless error.'" Rose, 871 F.2d at 342. Accord Hancock Indus. v. Schaeffer, 811 F.2d 225, 229 (3d Cir. 1987). Therefore, "the judgment may be affirmed if it appears that there is no set of facts on which plaintiffs could possibly recover." Rose, 871 F.2d at 342.

Although Cantekin contends it was procedural error for the court to convert the 12(b)(6) motion into a Rule 56 motion without notice, defendants argue that the court lacked jurisdiction over the pre-October 1986 claims. Therefore, defendants contend, the court properly converted the 12(b)(6) motion into a motion for summary judgment.

We hold that the court's failure to provide plaintiff with notice of its intention to convert the 12(b) motion into a Rule 56 motion was harmless error because the government knew about Dr. Bluestone's private funding before the October 27, 1986 amendment to the FCA. Under the pre-1986 amendment to the FCA, a district court lacked jurisdiction to consider a qui tam plaintiff's complaint if the complaint was "based upon evidence or information in the possession of the United States, or any agency, officer or employee thereof, at the time" the complaint was filed. 31 U.S.C. § 232(C). Therefore, where there is "evidence or information in the possession of the United States," the court cannot retain jurisdiction. United States v. Aster, 275 F.2d 281, 282-83 (3d Cir. 1960).

In an affidavit dated February 16, 1994, Dr. Earleen Elkins stated that "[d]uring the period between October 1979 and June 23, 1987, I was aware that Dr. Bluestone and the OMRC were conducting studies funded by private pharmaceutical companies to evaluate the efficacy of various antimicrobial agents." Affidavit of Earleen Elkins, Ph.D. ¶ 10. Later, on or about September 24, 1997, Dr. Elkins further stated that "[p]rior to October 1986, I was fully aware of the fact that Dr. Charles Bluestone was receiving substantial funding from private pharmaceutical companies to do drug efficacy studies at the same time that he was receiving

funding from NINCDS to do drug efficacy studies." Defendants' Opposition to Relator's Motion For Reconsideration Ex. A ¶ 4. Dr. Elkins, who at all relevant times hereto, was and is an employee of the federal government, swears that she knew about the private funding issue before October 1986.

Plaintiff argues, inter alia, that Dr. Elkins' knowledge was insufficient because she did not know the exact drug company from which Dr. Bluestone received private funding. Further, Cantekin contends that because Dr. Elkins had limited interaction with the grant funding process, her knowledge was insufficient. We disagree.

The language of the statute is clear and unambiguous; therefore, we must give effect to the plain meaning. Here, the material issue is whether the government knew that Dr. Bluestone, who was receiving federal funding, was also receiving private funding. The statute does not require that a certain quantum or type of information must be known before the statute applies. Rather, it requires that the government or a governmental employee possess sufficient evidence to enable the government "adequateley to investigate the case and to make a decision whether to prosecute." Pettis ex rel. United States v. Morrison-Knudsen Co., Inc., 577 F.2d 668, 673 (9th Cir. 1978).

Dr. Elkins, a federal governmental employee, knew that Dr. Bluestone was receiving private funding as well as funding from the government before October 1986. This knowledge and information adequately enabled Dr. Elkins to investigate the amount of funding, from whom Dr. Bluestone received such funding, and whether such funding was

inappropriate. Accordingly, this knowledge deprives the court of jurisdiction to consider the pre-October 1986 FCA claims.

In addition, because the relevant information was within the government's possession before October 1986, this further supports the conclusion that this court lacked jurisdiction to consider the pre-October 1986 FCA claims. See, e.g., United States v. Burmah Oil Co. Ltd., 558 F.2d 43, 46 (2d Cir.) (finding that the court lacked jurisdiction where the evidence and information was in the Justice Department files), cert. denied, 434 U.S. 967 (1977). Accord United States ex rel. MacFarlane v. Hutchinson, 519 F. Supp. 563, 564-65 (D. Colo. 1981) (holding that because all fifty-eight allegedly false claims were within the government's possession at the time suit was filed, jurisdiction was lacking); United States v. Armour & Co., 146 F. Supp. 546, 549 (D.D.C. 1956) (finding, inter alia, that the evidence or information on which the plaintiff's suit was based was in the possession of the United States because the government possessed contracts, invoices, and vouchers which disclosed on their face improper charges), aff'd, 245 F.2d 90 (D.C. Cir.), cert. denied, 358 U.S. 834 (1958).

Our review of numerous documents establishes that the government possessed information indicating that Dr. Bluestone was receiving private funding to support his research prior to October 1986. See, e.g., Exhibits to Earleen Elkins' Deposition at Tabs 4, 9, 10, 11-14, 18, 19, 21, 23-24, 30, 32, 33. There are also numerous references in various documents, such as Dr. Bluestone's non-competing continuation applications (progress reports), competing renewal applications, and an application for supplemental

funds, in which he admits that he was receiving private funding, as well as funding from the government. Furthermore, several members on the review committee that evaluated Dr. Bluestone's renewal application submitted affidavits stating that prior to October 1986, they knew that Dr. Bluestone was receiving private funding. See, e.g., Defendants' Opposition to Relator's Motion For Reconsideration at Tabs C, D and E. As such, the information was within the government's possession before plaintiff filed suit. Jurisdiction is negated by the government's possession of this information.

Having provided plaintiff another opportunity to rebut the conclusion that the government knew about Dr. Bluestone's private funding, Cantekin has failed to provide any evidence establishing that the government did not know about Dr. Bluestone's private funding. Accordingly, the court lacked jurisdiction to hear plaintiff's pre-1986 claims. Therefore, the conversion of the 12(b)(6) motion into a Rule 56 motion for summary judgment, without providing notice to the parties, was harmless error.

II. THE POST-OCTOBER 27, 1986 FCA CLAIMS

Plaintiff originally argued, citing case law, that if the court should deny the motion for reconsideration and find that the government knew of Dr. Bluestone's private funding, the court should "direct the Clerk to enter judgment for the False Claim Act defendants on all False Claims Act claims." Plaintiff's Brief at pgs. 21-22. Plaintiff now contends that the post-October 26, 1986 FCA claims should survive irrespective of how the court decides the motion for reconsideration.

Defendants contend that Cantekin is not an "original source," as required by the statute, and therefore the post-October 26, 1986 FCA claims should be dismissed. Specifically, defendants argue that plaintiff is not an "original source" because Cantekin was not the source of the public disclosure of the information and because some other party informed the government that Dr. Bluestone was receiving private funds as well as public funds for research.

Both parties agree that sections 3730(e)(4)(A) and (B) govern the viability of plaintiff's post-October 26, 1986 FCA claims. Section 3730(e)(4)(A) provides:

> No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C.A. § 3730(e)(4)(A).

Section 3730(e)(4)(B) defines "original source" as "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the government before filing an action under this section which is based on the information." 31 U.S.C.A. § 3730(e)(4)(B). Thus, we must determine whether there has been public disclosure of the

information and, if so, whether Cantekin is an "original source" as contemplated by the statute.

Public disclosure, within the meaning of the statute, encompasses the "disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media." 31 U.S.C.A. § 3730(e) (4)(A). As noted by the Court of Appeals, "the Act bars suits based on publicly disclosed 'allegations or transactions,' not information." United States ex rel. Dunleavy v. County of Delaware, 123 F.3d 734, 740 (3d Cir. 1997) (citations omitted).

The Court of Appeals has articulated a two-prong test to determine whether there has been public disclosure: (1) "whether the source is one recognized by the Act"; and (2) "whether the extent of disclosure is sufficient to support the conclusion that the information contained therein is now public within the meaning of the Act." Id. at 744. Section 3730(e)(4)(A) identifies the sources for disclosure. See 31 U.S.C.A. § 3730(e)(4)(A). "The prevailing view is that this list constitutes an exhaustive rendition of the possible sources." Dunleavy, 123 F.3d at 744. Accord United States ex rel. Williams v. NEC Corp., 931 F.2d 1493, 1499 (11th Cir. 1991).

Neither Cantekin nor defendants dispute that there was public disclosure of the information. Indeed, we find that the Congressional Subcommittee Hearing, held on September 29, 1988, which considered, inter alia, several of plaintiff's allegations, falls squarely within the statutory definition of public disclosure. Moreover, because the allegations were

aired during a public hearing and subsequently published, the extent of disclosure was "sufficient to support the conclusion that the information contained therein is now public" within the meaning of the Act.

Having found that there was public disclosure, we must next consider whether Cantekin was the "original source" of the information. In construing the term "original source," the Court of Appeals has "imposed a conjunctive requirement – direct and independent – on qui tam plaintiffs." United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co., 944 F.2d 1149, 1160 (3d Cir. 1991). The word "direct" is usually interpreted as "marked by absence of intervening agency." Id. at 1160. As noted by the Court of Appeals, "the paradigmatic 'original source' is a whistleblowing insider." Id. at 1161.

Defendants concede that "Relator Cantekin did have direct and independent knowledge of the allegedly actionable information and did voluntarily provide that information to the Government prior to filing this suit." Defendants' January 20, 1998 Letter Brief pg. 2. However, defendants contend that because plaintiff was not the source of the public disclosure and because the government already knew about the private funding, Cantekin cannot be the "original source" as contemplated by the statute. We disagree.

First, the plain language of the statute requires that the qui tam plaintiff must have direct and independent knowledge and must have disclosed the information to the government prior to filing his or her complaint. Defendants readily concede that plaintiff satisfies each of these requirements. Moreover, the statute itself does not require that the original

source provide the information to the entity that made the public disclosure. Rather, it requires that the relator "voluntarily provide[] the information to the Government before filing an action." See 31 U.S.C.A. § 3730(e)(4)(B). Thus, "[u]nless exceptional circumstances dictate otherwise, '[w]hen we find the terms of a statute unambiguous, judicial inquiry is complete.'" Burlington N.R.R. v. Oklahoma Tax Comm'n, 481 U.S. 454, 461 (1987) (quoting Rubin v. United States, 449 U.S. 424, 430 (1981)).

Furthermore, contrary to defendants' argument, even under the test articulated in Wang v. FMC Corp., 975 F.2d 1412 (9th cir. 1992), and United States ex rel. Dick v. Long Island Lighting Co., 912 F.2d 13 (2d Cir. 1990), plaintiff is an original source. In Wang and Dick, the courts imposed the additional requirement that the relator must have directly or indirectly been the source of information to the entity that publicly disclosed the allegations. Wang, 975 F.2d at 1419-20; Dick, 912 F.2d at 16.

As discussed, the Subcommittee Hearing constituted public disclosure of the allegations. A cursory review of the published House Report establishes that plaintiff, rather than some other party, was the direct source of the information for the Subcommittee Hearing Investigation into Dr. Bluestone's private funding. Although the government possessed this information in its files, and although Dr. Elkins knew about the private funding issue, they did not cause this information to be publicly disclosed. Rather, plaintiff was directly involved in the public disclosure of this information, as evidenced by the Subcommittee's reliance on plaintiff's testimony and his May 1987 allegations. Therefore, under Wang and Dick, plaintiff is an "original source."

Finally, defendants argument that "by the time . . . Relator Cantekin raised his allegations of fraud, the Government was already in possession of the allegedly actionable information," is without force. Under the pre-October 1986 FCA law, governmental knowledge was a jurisdictional defense to an action brought by a qui tam plaintiff. United States ex rel. Lindenthal v. General Dynamics Corp., 61 F.3d 1402, 1408 (9th Cir. 1995), cert. denied, __U.S. __ , 116 S. Ct. 1319 (1996). After the 1986 amendment, however, governmental knowledge no longer provides the same defense. Accordingly, we find that plaintiff has satisfied the statutory requirements of 31 U.S.C.A. § 3730(e)(4)(A) and (B) and may proceed with his post-October 1986 claims.

An appropriate order will follow.

/s/_____
Donald E. Ziegler
Chief Judge

DATED: February 9, 1998

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

[Filed February 9, 1998]

No. 91-0715

UNITED STATES OF AMERICA ex rel. ERDEM I. CANTEKIN, *Plaintiff*,

v.

UNIVERSITY OF PITTSBURGH, a non-profit Pennsylvania corporation; CHILDREN'S HOSPITAL OF PITTSBURGH, a non-profit Pennsylvania corporation; and CHARLES D. BLUESTONE, an individual, *Defendants*.

ORDER

AND NOW, this 9th day of February, 1998, after consideration of the plaintiff's motion for reconsideration, pursuant to Rule 59(e) of the Federal Rules of Civil Procedure, and the written submissions of the parties,

IT IS ORDERED that the motion of plaintiff (doc. no. 123), Erdem I. Cantekin, for reconsideration shall be and hereby is denied.

IT IS FURTHER ORDERED that summary judgment motions with respect to the post-October 27, 1986 FCA claims shall be filed, if appropriate and desired, on or before March 6, 1998.

IT IS FURTHER ORDERED that, if the parties desire additional discovery with respect to the post-October 27, 1986 claims, counsel shall file appropriate motions.

/s/_____
Donald E. Ziegler
Chief Judge

cc: Counsel of Record

APPENDIX G

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

[Filed August 25, 1997]

No. 91-0715

UNITED STATES OF AMERICA ex rel. ERDEM I. CANTEKIN, *Plaintiff*,

v.

UNIVERSITY OF PITTSBURGH, a non-profit Pennsylvania corporation; CHILDREN'S HOSPITAL OF PITTSBURGH, a non-profit Pennsylvania corporation; and CHARLES D. BLUESTONE, an individual, *Defendants*.

OPINION

ZIEGLER, Chief Judge

Pending before the court is the motion of defendants the University of Pittsburgh, Children's Hospital of Pittsburgh and Charles D. Bluestone, to dismiss plaintiff's pre-October

27, 1986 False Claims Act claims, as well as defendants' motion for partial summary judgment as to plaintiff's claims of scientific fraud, and as to all claims that were brought originally as Civil Action No. 95-0552. For the reasons that follow, defendants' motion to dismiss will be granted, defendants' motion for partial summary judgment as to the claims of scientific fraud will be denied, and defendants' motion for summary judgment as to the 1995 action will be granted in part and denied in part.

In his original complaint, plaintiff alleges, in sum, that defendants violated the False Claims Act ("FCA"), 31 U.S.C. § 3729 et seq., in relation to grant applications to research the effects of antibiotics in treating otitis media (middle ear disease). Although the United States of America is the named plaintiff, the FCA empowers Erdem I. Cantekin, as relator, to bring a qui tam action on behalf of the government. See 31 U.S.C. § 3729(c). Plaintiff alleges that defendants, through the Otitis Media Research Center ("OMRC"), made intentionally false statements on grant applications to the National Institute of Health ("NIH") because they did not inform the NIH that the lead researcher on the project, defendant Charles D. Bluestone, had received and continued to receive financial grants from private pharmaceutical companies in support of the same or similar research.

Motion to Dismiss

We first will address defendants' motion to dismiss pursuant to the recent Supreme Court decision in United States ex rel. Schumer v. Hughes Aircraft Co., ___ U.S. ___, 117 S.Ct. 1871 (1997). Prior to October 27, 1986, where a relator based a qui tam action on information already in the

government's possession. the statute directed the district court to dismiss the suit. 31 U.S.C. § 3730(b)(4) (1982). Congress, however, amended the statute to allow relators to bring qui tam actions based upon information previously known to the government, as long as the information was not publicly disclosed and the relator was the original source of the information. See 31 U.S.C. § 3730(e)(4)(A)(4) (1986).

Plaintiff initiated the instant action on April 29, 1991, alleging false claims by defendants which took place both before and after the 1986 amendment. On June 16, 1997, the Supreme Court held that the 1986 FCA amendment was not retroactive, and therefore claims made under it relating to pre-amendment activity must be analyzed pursuant to the prior statute. Hughes Aircraft, 117 S.Ct. at 1876. Defendants have moved to dismiss plaintiff's claims relating to alleged FCA violations that took place before the 1986 amendment became effective.

Plaintiff argues, however, that this action differs from Hughes. In Hughes, the alleged FCA violation occurred, and the government received the information relating to the violation, prior to the statute's amendment. Id. The Court specifically withheld judgment as to situations where the alleged violation took place before the amendment, but the notification took place after the amendment. Id. at n. 4. Plaintiff, as relator, asserts that his notification to the government in the instant claims took place only after the 1986 amendment. The Court of Appeals for the Ninth Circuit has held that, in such situations, the relator may pursue an action. United States ex rel. Anderson v. Northern Telecom, Inc., 52 F.3d 810 (9th Cir. 1995). Defendants argue, however, that the government, through the NIH, was aware

of the conduct that plaintiff alleges violated the FCA before October 27, 1986.

Plaintiff alleges in his complaint and elsewhere that he brought the allegations to the attention to the NIH, and therefore the government, in May 1987, after the amendment date. See, e.g., Complaint at ¶ 36 (Doc. No. 1); Aff. of Erdem I. Cantekin at 2 (Doc. No. 94). Defendants, however, have submitted evidence via affidavit that the government was aware of the these allegations prior to the amendment date.

Because both parties have submitted and relied on materials beyond the pleadings, defendants' motion to dismiss should be treated as a motion for summary judgment. See Fed.R.Civ.P. 12(b). Summary judgment is appropriate when there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). In considering a motion for summary judgment, we must examine the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in favor of that party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986).

In an affidavit, Earleen Elkins, the health science administrator for the National Institute of Neurological and Communicative Disorders and Stroke, stated that "[d]uring the period between October 1979 and June 23, 1987, I was aware that Dr. Bluestone and the OMRC were conducting studies funded by private pharmaceutical companies to evaluate the efficacy of various antimicrobial agents." (Doc. No. 90; App to Def. Br. at 4, F.2.). The affidavit further states that Elkins believed that review committee members and other government personnel were "aware of numerous

studies being conducted by [Bluestone] that were funded by pharmaceutical companies." Id. at 3. Finally, she notes that "the non-competing continuation applications (progress reports), competing renewal applications and an application for supplemental funds submitted by [Bluestone] after the initial grant application contain many references to studies that Dr. Bluestone and the OMRC were conducting that were funded by private pharmaceutical companies." Id. at 3-4. Excerpts from those grant applications were attached to the affidavit. Id.

Plaintiff has submitted no evidence that rebuts this assertion by defendants. While he has shown that he informed the NIH of the alleged FCA violations in May 1987, plaintiff has not shown evidence that the government was unaware of the information before that time. In view of the uncontested evidence, we find that the government was aware of the allegedly actionable information before the FCA amendments in October 1986. Therefore, pursuant to the teachings of Hughes Aircraft, we will grant defendants' motion to dismiss. We further will direct the parties to outline, via letter memorandum, the remaining FCA claims.

Claims of Alleged Scientific Fraud

Defendants also have moved for summary judgment as to what they consider to be one of plaintiff's claims in his original qui tam complaint. (Doc. no. 1). Specifically, defendants seek judgment as to paragraph 26 of the original complaint, which reads as follows:

> 26. In addition, defendant Bluestone falsely and fraudulently published the results of the

> AB-OME-I study in a manner so as to make the antibiotic tested, Amoxicilin, appear to be more effective than placebo when, in fact, the actual data of the study did not support that conclusion.

Complaint at ¶ 26.

Defendants argue that the resultant paper and analysis of the collected data were not fraudulent; rather amounted it a scientific conclusion, and therefore is not actionable under the FCA even if it was incorrect from a scientific point of view. See Wang v. FMC Corp., 975 F.2d 14512, 1421 (9th Cir. 1992) (stating that the FCA "is concerned with ferreting out 'wrongdoing,' not scientific errors"); see also United States ex rel. Anderson, 52 F.2d at 815; Hindo v. University of Health Sciences, 65 F.3d 608, 613 (7th Cir. 1995), cert. denied, 116 S.Ct. 915 (1996). Plaintiff agrees, and indeed stipulates that he will not contend that "the manner in which the NIH-funded studies were conducted or the conclusions which were drawn by Dr. Bluestone and his colleagues from the NIH-funded studies constitute 'false statements' independently actionable under the FCA." Pl. Br. at 12-13.

Plaintiff argues, however, that this statement was not a separate "claim" in his complaint. Rather, he asserts that the statement, and evidence supporting it, are relevant to his claim for damages. Defendants state that they will file a motion in limine as to the evidence concerning the results of Dr. Bluestone's paper. We find that such a motion is a more appropriate forum to discuss the relevance and merits of this section of plaintiff's claim. We therefore will deny

defendants' motion for partial summary judgment as to plaintiff's claim of scientific fraud.

Summary Judgment as to 1995 Action

Defendants also have moved for summary judgment as to the claims brought by plaintiff Cantekin individually in Pennsylvania state court in 1995. Plaintiff's 1995 amended complaint, sets forth three claims including whistle blower protection pursuant to federal and Pennsylvania statutes, a count of civil conspiracy, alleging that the conspirators set out "to punish [plaintiff] and destroy his career in academic medicine," and a breach of contract claim against the University of Pittsburgh. See First Amended Complaint at 29-39 (Doc. No. 52). Plaintiff alleges that the University of Pittsburgh, Charles Bluestone, Eugene N. Myers and Thomas P. Detre are liable under each of the claims, except for the breach of contract claim, which involves only the University. Those claims were removed by defendants to federal court and consolidated with this action by order dated May 30, 1995. (doc. no. 44).

We first note that plaintiff consents to the dismissal of his whistle blower action pursuant to Pennsylvania Law as time-barred. See 43 P.S. § 1424(c); Pl. Br. at 2. We further note that all parties agree that plaintiff's federal whistle blower action cannot be brought against individuals. See Pl. Br. at 2, 20-22, Def. Br. at 30-31. Therefore, we will grant defendants' motion as to these issues. As only one defendant, the University, remains in this action, plaintiff also has consented to the dismissal of his claim of civil conspiracy. Id.

As to the University, plaintiff's federal whistle blower claim arises under 31 U.S.C. § 3730(h), which states, in pertinent part, that:

> Any employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of lawful acts done by the employee or others in furtherance of an action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section, shall be entitled to all relief necessary to make the employee whole.

Actions under 31 U.S.C. § 3730 may not be brought "more than 6 years after the date on which the violation of section 3729[1] is committed." 31 U.S.C. § 3731(b). Because section 3731(b) acts as a statute of repose rather than as a statute of limitations, the relevant activity for determining the timeliness of plaintiff's claim is the date of the alleged violation of the FCA, not the alleged date of discrimination against the whistle blower. See Neal v. Honeywell, Inc., 33 F.3d 860, 865 (7th Cir. 1994); Black's Law Dictionary at 1411 (6th ed. 1990) (explaining that a statute of limitations extinguishes the right to prosecute an accrued cause of action after period of time, whereas a statute of repose "limits

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[1] 31 U.S.C. § 3729 provides for liability where a person makes false claims to the federal government.

potential liability by limiting [the] time during which [a] cause of action can arise").

FCA violations accrue when individuals make the allegedly false claims to the government. See United States v. Van Oosterhout, 898 F. Supp. 25 (D.D.C.) aff'd, 96 F.3d 1491 (D.C. Cir. 1995); United States v. Rivera, 55 F.3d 703, 707, 709-12 (1st Cir. 1995); United States v. Ekelman & Assoc., 532 F.2d 545, 552 (6th Cir. 1976). In the instant action, plaintiff alleges that defendants' false claims to the government were made between 1979 and 1987. Complaint at 3 (Doc. No. 1). Plaintiff's claims, therefore, are timely if brought before some time in 1993.

The University argues that plaintiff's claims are time-barred because he filed his action in state court on March 10, 1995. Plaintiff argues, however, that he tolled the effects of section 3731(b) in 1991 by filing a praecipe for a writ of summons in Pennsylvania state court on October 28, 1991. See Cantekin Aff. Ex. H at 3 (Doc. No. 94). Under Pennsylvania law, the filing of a praecipe for a writ of summons tolls the applicable statute of limitations. Lamp v. Heyman, 366 A.2d 882, 885 (Pa. 1976). Pursuant to Pa.R.C.P. 401(b) and Lamp, the writ may be reissued at any time within an additional time period equal to the applicable statute of limitations. Young v. Pennsylvania Dept. of Transp., 690 A.2d 1300, 1302 (Pa. Super. 1997) .

Plaintiff's October 1991 filing was in the Court of Common Pleas, Allegheny County, Civil Division, No. G.D. 91-19224. His 1995 state court action, before removal and consolidation with this action, was filed at G.D. 95-4132. Defendant argues that because they were filed under separate

numbers, the complaint does not relate back to the original praecipe for writ of summons. In Beck v. Minestrella, 401 A.2d 762, 763 (Pa. Super. 1979), however, the Pennsylvania Superior Court held that although preferable, it is not necessary for a complaint to be filed at the same docket number as a praecipe for writ of summons. Plaintiff argues that his 1995 state court complaint relates to the praecipe for writ of summons in 1991, as they name the same relevant defendants. Further, contemporaneous evidence demonstrates that plaintiff transmitted a proposed complaint to the University in 1991 that was similar to the complaint ultimately filed in 1995.

The University also notes that plaintiff's 1995 state court complaint does not allege a violation of the federal whistle blower law. Def. Reply Br. at 18. Becasue the original complaint did not contain such allegations, the University concludes that plaintiff should not be allowed to pursue them. Id. We note, however, that defendants' based their argument for removal of the 1995 action on the premise that plaintiff was "pursuing what are truly federal claims," i.e. the federal whistle blower statute, notwithstanding that the complaint contained no federal cause of action. (C.A. No. 95-0552, doc. no. 1 at 3). Defendant never moved to dismiss plaintiff's federal whistle blower claim on the basis that it did not "relate back" to the conduct alleged, and we decline to do so here.

We therefore find that plaintiff's whistle blower action against the University pursuant to 31 U.S.C. § 3730(h) is timely, and will deny summary judgment as to this part of the University's motion.

Breach of Contract Claim

Finally, we will address the University's motion for summary judgment as to plaintiff's breach of contract claim. In his amended complaint, plaintiff alleges that the actions taken by the University, starting in 1986, violated his employment contract and acted as a "constructive termination." (Doc. No. 52 at ¶ 143). The actions included freezing plaintiff's salary and depriving him of "any meaningful opportunity to function as a member of the faculty." Id.

Plaintiff alleges that the breach of contract took place starting in August 1986, when he was removed as director of research of the department of Pediatric Otolaryngology. Pl. Br. at 4. His asserted employment contract is based on a concept of tenure, and by his own admission, is vague and "does not contain any detail from which a court could define duties which the university must assign to a tenured faculty member, or which it could take away from a tenured faculty member." Id. at 34.

In his complaint, plaintiff alleges that the breach of contract claim is based on the fact that the University had "annually and intentionally denied to plaintiff . . . any increase whatever in his salary, including the percentage increase allocated for 'non-merit' increases each year." Amended Complaint at ¶ 138. He also alleges that other members of the University at equal rank were given the non-merit increases, while he was not. Id. at ¶ 139. He argues that failure to give the increases in salary constituted constructive termination, as he was never given a reason for not receiving an increase in pay, or granted a hearing to rebut

the University's reasons. Id. Howver, plaintiff has produced no evidence that the denial of "non-merit" increases in salary without a hearing violates his employment contract, regardless whether the denials were in retaliation for his acts. Therefore, University's motion for summary judgment as to plaintiff's claim for breach of contract will be granted.

In his response brief, plaintiff also alleges that the University limited his First Amendment right to academic freedom. Pl. Br. at 34-35. Allegations of constitutional violations by the University may be brought under 42 U.S.C. § 1983. See Krynicky v. University of Pittsburgh, 742 F.2d 94, 97 (3d Cir. 1984). However, plaintiff has not alleged any such violation in his original or amended complaint. To the extent that plaintiff seeks to add a section 1983 claim to this now seven year old action, such a request will be denied.

Conclusion

In summary, we will grant defendants' motion to dismiss plaintiff's pre-October 27, 1986 FCA claims, and deny defendant's motion partial summary judgment as to plaintiff's claims of scientific fraud. Defendants' motion for summary judgment as to plaintiff's whistle blower claims, however, will be denied in part and granted in part.

An appropriate order shall follow.

/s/_____
Donald E. Ziegler
Chief Judge

DATED: August 25th, 1997
cc: Counsel of Record

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

[Filed August 25th, 1998]

No. 91-0715

UNITED STATES OF AMERICA ex rel. ERDEM I. CANTEKIN, *Plaintiff*,

v.

UNIVERSITY OF PITTSBURGH, a non-profit Pennsylvania corporation; CHILDREN'S HOSPITAL OF PITTSBURGH, a non-profit Pennsylvania corporation; and CHARLES D. BLUESTONE, an individual, *Defendants*.

ORDER

AND NOW, this 25th day of August, 1997, after consideration of the submissions of the parties,

IT IS ORDERED that the motion (document no. 110) of defendants the University of Pittsburgh, Children's Hospital of Pittsburgh and Charles D. Bluestone, to dismiss plaintiff's pre-October 27, 1986 False Claims Act claims be and hereby is granted.

IT IS FURTHER ORDERED that the motion (document no. 84) for summary judgment pursuant to Fed. R.Civ. P 56(c) as to the action formerly docketed at C.A. 95-0552 be and hereby is denied with respect to plaintiff's claims under the federal whistle blower statute, 31 U.S.C. § 3730(h) against the University of Pittsburgh.

IT IS FURTHER ORDERED that the motion is granted in all other respects.

IT IS FURTHER ORDERED that the motion (document no. 85) for summary judgment pursuant to Fed. R.Civ. P 56(c) as to plaintiff's claim of alleged scientific fraud be and hereby is denied.

IT IS FURTHER ORDERED that the parties shall submit, by letter brief, a statement of the claims that remain in this action within 30 days.

/s/_____
Donald E. Ziegler
Chief Judge

cc: Counsel of Record

APPENDIX H

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

[Filed June 20, 1996]

No. 91-0715

UNITED STATES OF AMERICA ex rel. ERDEM I. CANTEKIN, *Plaintiff*,

v.

UNIVERSITY OF PITTSBURGH, CHILDREN'S HOSPITAL OF PITTSBURGH, and CHARLES D. BLUESTONE, *Defendants*.

ORDER OF COURT

AND NOW, this 20th day of June, 1996,

IT IS ORDERED that the motion (document no. 71) of defendants, University of Pittsburgh, Children's Hospital of Pittsburgh, and Charles D. Bluestone, to strike the affidavits filed by the relator, Erdem I. Cantekin, in opposition to summary judgment be and hereby is denied.

IT IS FURTHER ORDERED that the motion (document no. 56) of defendants for summary judgment be and hereby is denied. Viewing the evidence in the light most favorable to plaintiff, we hold that genuine issues of material fact exist which preclude the entry of judgment as a matter of law on the False Claims Act asserted by the relator against defendants. Triable issues of material fact include but are not limited to: (1) whether defendants made an intentionally false application to the National Institute of Health ("NIH"), (2) whether the NIH was aware, in deciding to award a grant to support defendants' research in treating otitis media middle ear disease), that Dr. Bluestone had received and continued to receive financial grants from private pharmaceutical companies in support of the same or similar research, and (3) assuming that the NIH did not know of the private support, whether it would have awarded the grant to defendants if it had known. In view of the conflicting evidence of record, none of these issues is susceptible to summary judgment.

/s/_____
Donald E. Ziegler
Chief Judge

cc: Counsel or record

APPENDIX I

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

[Filed May 22, 2000]

No. 98-3552

UNITED STATES OF AMERICA, ex rel. ERDEM I. CANTEKIN, an individual

v.

UNIVERSITY OF PITTSBURGH, a non-profit Pennsylvania corporation; CHILDREN'S HOSPITAL OF PITTSBURGH, a non-profit Pennsylvania corporation; CHARLES D. BLUESTONE, an individual;

United States of America, ex rel. Erdem I. Cantekin,
Appellant

On Appeal from the United States District Court
for the Western District of Pennsylvania
(D.C. Civ. No. 9l-cv-00715)
District Judge: Hon. Donald E. Ziegler

SUR PETITION FOR REHEARING

BEFORE: BECKER, Chief Judge, SLOVITER, MANSMANN, GREENBERG, SCIRICA, NYGAARD, ALITO, ROTH, MCKEE, RENDELL, STAPLETON* and COWEN* Circuit Judges

The petition for rehearing filed by the Appellant in the above-entitled case, having been submitted to the judges who participated in the decision of the this court and to all other available circuit judges in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges in regular active service not having voted for rehearing by this court in banc, the petition for hearing is hereby DENIED.

By the Court

/s/_____
United States Circuit Judge

DATED: May 22, 2000

---

* Judge Stapleton's and Judge Cowen's votes are limited to panel rehearing only.

APPENDIX J

Union Calendar No. 430
101st Congress 2nd Session

HOUSE OF REPRESENTATIVES

Report 101-688

ARE SCIENTIFIC MISCONDUCT AND CONFLICTS OF INTEREST HAZARDOUS TO OUR HEALTH?

September 10, 1990.--Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. Conyers, from the Committee on Government Operations, submitted the following

NINETEENTH REPORT

together with

DISSENTING AND ADDITIONAL VIEWS
Based On A Study By the Human Resources And Intergovernmental Relations Subcommittee

On August 2, 1990, the Committee on Government Operations approved and adopted a report entitled "Are Scientific Misconduct and Conflicts of Interest Hazardous to Our Health?" The Chairman was directed to transmit a copy

APPENDIX J

Union Calendar No. 430

101st Congress, 2d Session - - - - - - House Report 101-688

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BY THE

COMMITTEE ON GOVERNMENT OPERATIONS

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DISSENTING AND ADDITIONAL VIEWS

September 10, 1990. - Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

U.S. Government Printing Office
Washington: 1990

32-902

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(II)

LETTER OF TRANSMITTAL

HOUSE OF REPRESENTATIVES
Washington, DC, September 10, 1990

Hon. THOMAS S. FOLEY,
Speaker of the House of Representatives,
Washington, D.C.

DEAR MR. SPEAKER: By direction of the Committee on Government Operations, I submit herewith the committee's nineteenth report to the 101st Congress. The committee's report is based on a study made by its Human Resources and Intergovernmental Relations Subcommittee.

JOHN CONYERS, Jr., *Chairman.*

(III)

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Union Calendar No. 430
101st Congress 2nd Session

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September 10, 1990.--Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. Conyers, from the Committee on Government Operations, submitted the following

NINETEENTH REPORT

together with

DISSENTING AND ADDITIONAL VIEWS

* * *

pp. 1-10

Based On A Study By the Human Resources And Intergovernmental Relations Subcommittee

On August 2, 1990, the Committee on Government Operations approved and adopted a report entitled "Are Scientific Misconduct and Conflicts of Interest Hazardous to

Our Health?" The Chairman was directed to transmit a copy to the Speaker of the House.

I. Introduction

Under the rules of the House of Representatives Rule X, 2(b)(2), the Committee on Government Operations is authorized to "review and study, on a continuing basis, the operation of Government activities at all levels with a view to determining their economy and efficiency." The committee has assigned this responsibility, as it pertains to the Department of Health and Human Services (HHS) to the Human Resources and Intergovernmental Relations Subcommittee.

Pursuant to its authority, the subcommittee conducted an oversight investigation of the Federal role in preventing and investigating scientific misconduct and conflicts of interest. The subcommittee hearings focused on the U.S. Public Health Service, particularly the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA).

The NIH consists of 13 institutes that conduct and support biomedical research into the causes, prevention, and cure of diseases.[1] These institutes include the National Cancer Institute; the National Heart, Lung, and Blood Institute; the National Eye Institute; the National Institute of Allergy and Infectious Diseases; the National Institute of

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[1] The United States Government Manual, revised July 1, 1989. Washington, D.C.: GPO, p.313.

Diabetes and Digestive and Kidney Diseases; the National Institute of Arthritis and Musculoskeletal and Skin Diseases; the National Institute of Child Health and Human Development; the National Institute on Aging; the National Institute of Dental Research; the National Institute of Environmental Health Sciences; the National Institute of General Medical Sciences; the National Institute on Deafness and Other Communication Disorders; and the National Institute of Neurological and Communicative Disorders and Stroke. NIH also includes other facilities, such as the National Center for Nursing Research, the Clinical Center, and the Fogarty International Center. NIH supports research training and the development of research resources, and disseminates biomedical information. The research appropriation for FY 1990 is $7.32 billion.[2]

ADAMHA is the Public Health Service agency that provides a national focus for the Federal effort to increase knowledge and promote effective strategies to improve mental health and deal with substance abuse.[3] It is comprised of three institutes: the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse. ADAMHA conducts and supports research on the biological, psychological behavioral, and epidemiological aspects of substance abuse and mental health and mental illness as well as the delivery of services

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[2] Davey, M.E. (1990) Research and Development Funding: FY 1991, *CRS Issue Brief*. P. 10.

[3] The U.S. Government Manual 1989/90. Op. cit. p. 306.

and treatment programs.[4] ADAMHA also supports the training of scientists to conduct such research, gathers national data on these problems, collaborates with a range of public and private organizations to improve mental health and substance abuse programs; and disseminates information to the public and the scientific community.[5] The ADAMHA research appropriation for FY 1990 is $763.7 million.[6]

On April 11, 1988, the subcommittee held its first hearing that focused on scientific fraud and misconduct.[7] This hearing included testimony from Dr. Robert L. Sprague, professor at the Institute for Research on Human Development at the University of Illinois, Urbana-Champaign; Dr. Jerome Jacobstein, director of nuclear medicine at the Graduate Hospital, University of Pennsylvania; Dr. June Price Tangney, a psychologist on the faculty at Bryn Mawr College in Pennsylvania; two scientists from the National Institutes of Health (NIH): Dr. Ned Feder and Mr. Walter Stewart; Dr. Katherine Bick, then Deputy Director for Extramural Research (NIH), accompanied by Mary Miers, Institutional

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[4] Ibid.

[5] Ibid.

[6] These statistics were provided by the Congressional Research Service (CRS) and are available in subcommittee files.

[7] Hearing before a subcommittee of the Committee on Government Operations, U.S. House of Representatives, "Scientific Fraud and Misconduct and the Federal Response." April 11, 1988, hereafter referred to as Hearing, April 11, 1988.

Liaison Officer; and Dr. Rex Cowdry, Acting Deputy Director of the National Institute of Mental Health (NIMH).

On September 29, 1988, the subcommittee held a second hearing, focusing on financial conflicts of interest among scientists.[8] This hearing included testimony from Jacques Galin, Jr., from New York City; Dr. Erdem Cantekin, professor of otolaryngology at the University of Pittsburgh Medical School; Dr. Leonard Minsky, executive director of the National Coalition for Universities in the Public Interest; Dr. George M. Bernier, Jr., dean of the University of Pittsburgh Medical School, accompanied by Lewis Popper, general counsel to the university; Dr. Victor J. Marder, co-chief of the Hematology Unit at the University of Rochester, Richard Kusserow, the Inspector General of the Department of Health and Human Services; and Dr. James Wyngaarden, then Director of NIH, accompanied by Dr. Katherine L. Bick, then Deputy Director for Extramural Research, and Dr. Charles R. McCarthy, Director of the Office of Protection from Research Risks at NIH.

On June 13, 1989, the subcommittee held a third hearing on conflicts of interest among scientists.[9] This hearing

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[8] Hearing before a subcommittee of the Committee on Government Operations, U.S. House of Representatives, "Federal Response to Misconduct in Science: Are Conflicts of Interest Hazardous to Our Health?" September 29, 1988, hereafter referred to as Hearing, September 29, 1988.

[9] Hearing before a subcommittee of the Committee on Government Operations, U.S. House of Representatives, "Is Science for Sale? Conflicts of Interest vs. the Public Interest,"

included testimony from Dr. Sheldon Krimsky, associate professor at Tufts University, and chairman of the Committee on Scientific Freedom and Responsibility of the American Association for the Advancement of Science; Dr. David Noble, professor at Drexel University, accompanied by Dr. Leonard Minsky of the National Coalition for Universities in the Public Interest; Dr. George D. Lundberg, editor of the Journal of the American Medical Association; Dr. Paul E. Gray, president of the Massachusetts Institute of Technology; Dr. David Blumenthal, senior vice president of Brigham and Women's Hospital and faculty member at Harvard Medical School; Dr. Patricia K. Woolf of the Woodrow Wilson School of Princeton University; Dr. James Wyngaarden, Director of the National Institutes of Health, accompanied by Dr. William F. Raub, Deputy Director of NIH; Dr. Katherine L. Bick, Deputy Director for Extramural Research; and Dr. Earleen Elkins, Science Administrator; and Mr. Erich Bloch. Director of the National Science Foundation.

II. BACKGROUND

In FY 1990, the Federal Government will spend approximately $21 billion for basic and applied research.[10] More than $7 billion will be for NIH research, and approximately 62 percent of those funds will be provided to colleges and universities.[11] ADAMAH research totals $763.7

June 13, 1989, hereafter referred to as Hearing, June 13, 1989.

[10] These statistics were provided by CRS and are available in subcommittee files.

[11] Ibid., p. 47.

million; 55 percent of which will be provided to colleges and universities.[12]

Scientific and biomedical research enjoys enormous support from Congress and the American public. However, during the last decade, there have been several cases of scientific fraud and misconduct that have received widespread attention. Federal agencies, congressional committees, scientific journals, and the research and academic communities have begun to question whether more needs to be done to prevent and respond to allegations of scientific misconduct.[13]

Science makes important contributions to improving health and the quality of life. The advancement of science is based on two pillars: the honesty of each scientist and the ability to replicate research findings to make sure they are correct.[14]

Scientific fraud has been defined in a variety of ways, that have differing legal and practical implications. Virtually all definitions share the tenet that scientific fraud is the

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[12] Ibid.

[13] Littlejohn, M.J. Matthews, C.M. *Scientific Misconduct in Academia: Efforts to Address the Issue*. CRS Report for Congress, June 30, 1989, p. 6. This report will be referred to as the CRS Misconduct Report.

[14] Cassidy, M.M. and Shamoo, A.E. (1989). First International Conference on Scientific Data Audit Policies, and Quality Assurance, *Accountability in Research*, Vol. 1, pp. 1-3.

"deliberate misrepresentation of something as a fact by someone who knows that it is not."[15] The most blatant example of scientific fraud is to report "results" of experiments that were never performed, but misrepresenting how the research was conducted or the results of the research are also examples of fraud.[16] In addition, manipulation of statistics to make results "come out better" are generally considered "not quite fraud" but can represent attempts to "mislead others without actually lying."[17] Plagiarism and exploiting the work of others can also be considered fraud or misconduct. Honest errors, including self-deception, are usually not considered fraud or misconduct unless they stem from carelessness or the failure to take responsibility for the work;[18] regardless of the cause, such errors can seriously undermine the pursuit of scientific knowledge.

There are many possible reasons for scientific misconduct. Scientists testified that pressure to publish research, in order to obtain a better job or a promotion, could influence a scientist to misrepresent or fabricate data in order

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[15] Friedman, P.J. Responding to Allegations of Research Misconduct in the University, *Project on Scientific Fraud and Misconduct*. Report on Workshop Number Two of AAAS-ABA National Conference of Lawyers and Scientists, 1989, p.33.

[16] Ibid.

[17] Ibid.

[18] Ibid, pp. 34-35.

to publish more articles.[19] Pressure to become well known and respected in one's field could have a similar effect.[20] In some fields, particularly biomedicine and biotechnology, there can be financial rewards for misrepresenting or even fabricating data; for example, scientists whose results indicate that a new drug is effective can earn consulting fees, honoraria, and travel paid for by the company that makes the drug.[21] However, the extent to which these pressures and rewards influence scientific misconduct has not been proven.[22]

A major controversy has been whether scientific misconduct occurs frequently enough to be a major concern. In an often quoted 1987 editorial, the editor of *Science* claimed that 99.9999 percent of scientific reports "are

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[19] Hearing, April 11, 1988, testimony of Dr. Robert Sprague, professor at the Institute for Research on Human Development at the University of Illinois at Urbana-Champaign, pp. 106-107.

[20] Hearing, April 11, 1988, testimony of Dr. Robert Sprague, pp. 106-107; testimony of Dr. Jerome Jacobstein, director of nuclear medicine at the Graduate Hospital, University of Pennsylvania, p. 107.

[21] Hearing, September 29, 1988, testimony of Dr. Erdem Cantekin, Department of Otolaryngology, University of Pittsburgh Medical School, p. 47.

[22] See, for example, Woolf, P.K. (September 23, 1987). "Pressure to Publish" is a Lame Excuse for Scientific Fraud, *Chronicle of Higher Education*, p. A52.

accurate and truthful;"[23] however, scientists testified that this estimate is just an opinion, based on "vaporous dreams" since "there is very little evidence on the frequency of fraud in general. We simply don't know."[24] Other scientists have argued that "petty cheating" is quite common in science, and in their controversial book on scientific fraud, *Betrayers of the Truth,* two science journalists, Broad and Wade, concluded "the roots of fraud lie in the barrels, not the bad apples that occasionally roll into public view."[25] Dr. June Price Tangney, assistant professor of psychology at George Mason University, testified that even if misconduct is rare, "that argument, I think, should not be made to dismiss this as an insignificant issue. . . . Murder is relatively rare, yet we as a society have decided it is important to pay close attention to that kind of misdeed."[26]

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[23] Koshland, D.E. (January 9, 1987). Fraud in Science. *Science*. Vol. 235, p. 141.

[24] Hearing, April 11, 1988, testimony of Dr. Robert Sprague, Professor of the Institute for Research on Human Development at the University of Illinois at Urbana-Champaign, and Dr. Jerome Jacobstein, Director of Nuclear Medicine at the Graduate Hospital, University of Pennsylvania, p. 108.

[25] Glazer, S. (August 5, 1988). Combating Science Fraud. *Editorial Research Reports*, pp. 390-402; Hearing, April 11, 1988, testimony of Dr. Jerome Jacobstein, pp. 108-109.

[26] Hearing, April 11, 1988, testimony of Dr. June Price Tangney, who was a psychologist on the faculty of Bryn Mawr College, p. 109.

Based on the number of reported cases of scientific fraud and misconduct, it appears to be rare; however, it is unknown whether a large or small percentage of misconduct is reported. Dr. Tangney's research stands alone as the only study attempting to assess how academic researchers respond to suspected misconduct. In a study of 245 scientists at a large university, Dr. Tangney found that 32 percent of the scientists had suspected a colleague of falsifying data, but 54 percent of them made no effort to verify whether their suspicions were correct.[27] Similarly, 32 percent had suspected a colleague of plagiarism, but more than half did nothing about that either. Moreover, although half the scientists thought that a colleague who falsified data should be fired, only 30 percent believed that would actually happen. This research does not claim to determine the actual prevalence of scientific misconduct, but it provides important insight on how frequently suspected misconduct is not reported, and the perception among scientists of how a university would handle allegations of misconduct.

Regardless of the prevalence of scientific misconduct there is considerable concern about it. A recent poll found that 17 percent of the public believes that research fraud happens "a lot" and an additional 41 percent believes it happens "a fair amount."[28] As public concerns about scientific misconduct have increased, the scientific community has become more

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[27] Dr. Tangney's research results are presented in her testimony at the April 11, 1988, Hearing, pp. 100-102.

[28] The results of this AMA survey were published in *Physician's Weekly,* November 11, 1989, available in subcommittee files.

willing to address those concerns. For example, during the last few years, there have been several national meetings on the topic, the Institute of Medicine issued a report on the responsible conduct of research, the National Academy of Sciences (NAS) published a booklet on scientific integrity, and a new journal entitled *Accountability in Research was* published.

The most widely publicized cases of scientific misconduct in recent years have tended to involve physicians conducting biomedical research. It is not known whether scientific misconduct is more frequent among physicians, or if biomedical research misconduct is more likely to be reported by individuals and the media because of the implications for public health. If physicians are more likely to be guilty of scientific misconduct, it may be because physician researchers are less rigorously trained in scientific methods and values or because they are more likely to receive funds from companies whose drugs they are investigating. Those potential conflicts of interest may lead to misrepresentation of data; similarly, research funds and contributions from private industry could provide disincentives to a university to investigate any allegations. Such conflicts of interest have traditionally been essentially ignored by both the universities and HHS. Most universities have had no limit on the amount of money their faculty may accept for research honoraria, travel, consulting fees, or gifts from drug companies or other private sources[29]

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[29] A sample of documents describing university policies is available in subcommittee files.

Until recently, the major exception has been the University of California system, which requires disclosure of all financial interests in nongovernmental research sponsors, and restrictions on some arrangements.[30] However, some of the administrators who are responsible for the system in California have publicly expreased their opposition to it; the system is required by law, but the Director of Research and Public Policy at the University of California has criticized the policy as expensive, slow, and demanding.[31]

NIH and ADAMHA have no restrictions on conflicts of interest for grantees, although they must approve any outside financial arrangements for NIH employees that could pose potential conflicts of interest.[32] However, NIH grant applications *require* grantees to list all sources of funding for research projects when they apply for NIH funds and NIH regulations require all grantees to have policies for dealing with financial conflicts of interest.[33]

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[30] Guidelines on University-Industry Relations, University of California, Office of the resident, May 1989; available in subcommittee files.

[31] Cole, B., Equity Ownership and Conflict of Interest, HIH Conflict of Interest Forum, June 27-28, 1989; available in subcommittee files.

[32] Hearing, September 29, 1988, testimony of Dr. James Wyngaarden, NIH Director, p. 185.

[33] Ibid., pp. 186, 192.

When a scientist accuses another scientist of misconduct or conflicts of interest, it often results in either the whistleblower or the accused losing their job.[34] In several well-documented cases, the careers of honest whistleblowers have been jeopardized, perhaps irrevocably.[35] According to Dr. Paul Friedman, Associate Dean for Academic Affairs at the University of California at San Diego "the ethos of institutions, if not of science, favored quiet correction or suppression of problems, with hostility toward those who brought accusations."[36] In those cases that involve medical treatment, the University's failure to believe and disseminate evidence provided by the whistleblower may result in the public's exposure to drugs, devices, or procedures that are harmful.

At a scientific fraud workshop co-sponsored by the American Association for the Advancement of Science and the American Bar Association, Dr. Allan Mazur of Syracuse University discussed eight cases of alleged misconduct where a school or funding agency "seems to have mishandled an

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[34] *The Scientist*, Vol. 1, December 14, 1987, Special Section: Whistleblowing, pp. 11-12.

[35] Ibid.

[36] Testimony of Paul J. Friedman, Hearing before the Oversight and Investigations Subcommittee of the House Committee on Science, Space and Technology, June 28, 1989. p. 154.

allegation of research misconduct."[37] In trying to determine what caused mishandling of those cases, Dr. Mazur described three recurrent inappropriate patterns of response: (1) "old boy damage control," where colleagues who were close to the accused tended to minimize the degree of misconduct; (2) "abrasive whistleblower," where the whistleblower was judged to be petty or vindictive and therefore not taken seriously; and (3) "dilution of responsibility," where several universities or agencies shared responsibility for the investigation, and therefore no one conducted a thorough investigation.

PUBLIC HEALTH SERVICE INVESTIGATIVE PROCEDURES

In 1985, Congress passed the Health Research Extension Act (P.L. 99-158), which directed the Secretary of the Department of Health and Human Services and the NIH Director to develop regulations regarding how recipients of NIH grants and contracts should respond to allegations of scientific fraud.[38] In addition, the law requires that NIH funding of grant applications be contingent on the applicants' having established administrative mechanisms to review allegations and report them to the funding agency.[39] The law therefore requires the universities to investigate allegations of

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[37] AAAS-ABA, *Project on Scientific Fraud and Misconduct*, Report on Workshop Number Two, Op. cit. pp. 67-68.

[38] Op. cit. p. 7.

[39] Ibid.

misconduct, without interference or assistance from the Public Health Service.

When the subcommittee held its first hearing, on scientific conduct on April 11, 1988, NIH's scientific fraud consisted of three staff members, including supervision by Dr. Katherine Bick, the Deputy Director for Extramural Research, who was also responsible for overseeing all of the NIH's 50,000 grants to colleges, universities, and research institutions.[40] Neither of the other two staff members had training as auditors, investigators, or scientists.[41]

Several PHS investigations were reviewed by the subcommittee at the April 11, 1988, hearing, including those investigating Dr. Stephen Breuning at the University of Pittsburgh and Dr. Jeffrey Borer at Cornell Medical College. Witnesses described those initial PHS investigations as superficial and biased; for example, investigators sometimes interviewed only the persan accused of wrongdoing and the "whistle-blower," without interviewing any other knowledgeable colleagues. Typically, no attempts were made to look at the data that held the key to the investigation. For example, Dr. Jerome Jacobstein, the "whistle-blower" in the Borer case, testified:

> The initial investigation, conducted at the medical school, was so inept as to defy rational explanation. The most inexperienced

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[40] Hearing, April 11, 1998, testimony of Dr. Katherine Bick, Deputy Director for Extramural Research (NIH), pp. 156-7.

[41] Ibid.

> investigator should have known that you don't ask the foxes if they have dined on the chickens, at least not without checking their teeth for feathers. And yet that is precisely what happened. The NIH investigator spoke to Mr. Borer and two or three of his coauthors, asking these individuals whether my allegations were correct and, being solemnly assured that they were not, he dutifully packed up and returned home. He did not interview knowledgeable but uninvolved third parties, did not interview laboratory personnel or review laboratory procedures, and did not look at the data books. Nor did the NIH investigator ask me if I could explain the contradictions in testimony.[42]

In the Breuning case, the only ADAMHA investigation that was described at the hearing, there was general agreement that the final NIH investigation, conducted by a panel of outside experts, was accurate and thorough. However, there were serious problems with the investigation as well: for example, it took several years to complete, and meanwhile no attempts were made to issue an interim report in order to warn health professionals not to base treatment decisions on Breuning's fraudulent research. Even after the fraudulent work was detailed in the NIMH report, there was

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[42] Hearing, April 11, 1988, testimony of Dr. Jerome Jacobstein, p. 66.

considerable delay before NIMH retracted the published research in its own journal.[43]

At the September 1988 hearing, the HHS Inspector General (IG), Richard Kusserow, presented the results of a preliminary study of the NIH policies regarding scientific fraud and misconduct.[44] The IG concluded that HHS had "no central locus of responsibility or accountability for scientific misconduct" and that NIH had been handling such allegations "on an ad hoc basis resulting in inconsistencies."[45] The IG found that only 22 percent of NIH grantee institutions had "policies and procedures in place to deal with cases of scientific misconduct, as required by law" although 93 percent of grantee institutions with 100 or more awards each year had such policies. The IG criticized existing misconduct procedures as limited, and reported that more than half of the institutions with misconduct cases were in the process of revising their procedures.

The IG recommended that HHS publish a final rule on scientific PHS misconduct policies, and require that all grantee institutions submit their procedures on an annual basis

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[43] Hearing, April 11, 1988, testimony and supporting douments of Dr. Robert Sprague, pp. 3-65; testimony of Dr. Rex Cowdry, Deputy Director of NIMH, pp. 169-175.

[44] Hearing, Setpember 29, 1988, pp. 123-161. The final report was published in March 1989: Kusserow, R.P. *Misconduct in Scientific Research.* OAI-88-07-00420, March 1989, hereinafter referred to as the IG Report on *Misconduct in Scientific Research.*

[45] Ibid., p. ii.

"to assure compliance with the law."[46] Although the IG did not question that "the first line of responsibility for conducting an inquiry and/or investigation into an allegation of misconduct rests with the grantee institution," the report recommended that grantee institutions be required to immediately notify HHS if misconduct is detected or alleged, and that HHS monitor the university investigations and specify acceptable timeframes. The IG also recommended that university whistleblowers receive the same kind of protection provided Federal employees under current law.[47]

Following the congressional hearing held in 1988 and 1989, and the criticism of the IG, NIH and ADAMHA reorganized their scientific misconduct efforts into two offices: The Office of Scientific Integrity (OSI) and the Office of Scientific Integrity Review (OSIR).

The Office of Scientific Integrity is responsible for reviewing procedures set up by institutions, and requires annual reports assuring compliance with the rules and providing information about the number of inquiries, allegations, and investigations.[48] OSI reports to the Director of NIH, and is responsible for monitoring ongoing investigations conducted by universities, and for conducting its own investigations.[49]

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[46] Ibid., p iii.

[47] Ibid., p. iv.

[48] Ibid.

[49] Ibid., p. 17.

The Office of Scientific Integrity Review, established in the Office of the Assistant Secretary for Health, oversees the operations of all the research agencies of the Public Health Service, reviews their policies, and reviews "all final reports of investigations to assure that any findings and recommendations are sufficiently documented."[50] When scientific misconduct has been established, OSIR also makes final recommendatious to the Assistant Secretary for Health regarding sanctions. OSIR can conduct its own investigations as well.

On August 8, 1989, the PHS published its final rule on the "Responsibilities of Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science."[51] The rule covers 1,668 colleges, universities and other research institutions as of November 8, 1989.[52] In response to complaints from the scientific community, the rule was revised to make clear that scientific misconduct would not include "honest error or honest differences in interpretation or judgments of data."[53]

The NIH Final rule gives major responsibility for investigating scientific misconduct to the grantees, who are

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[50] *Federal Register,* August 8, 1989. Vol. 54, No. 151. P. 32443.

[51] Ibid., pp. 32446-32451.

[52] *Science Agenda,* Fall 1989, p. 5: available in subcommittee files.

[53] *Science Agenda,* Ibid.

required to notify OSI immediately when the grantee initiates an investigation.[54] It is expected that investigations will be completed within 120 days, and that a report will be immediately submitted to OSI. OSI reviews the university investigation to determine if it "has been performed in a timely manner and with sufficient objectivity, thoroughness and competence" and may perform its own investigation "if necessary."[55] Sanctions may be imposed by the university or HHS, and "an institution's failure to comply with its assurance and the requirements of the final rule may result in enforcement action against the institution, including loss of funding."[56]

III. 10 CASES: BACKGROUND AND FINDINGS

The examples of scientific fraud and misconduct cases summarized below represent a range of questionable scientific behavior, including plagiarism, fabricating data, misrepresenting the way the study was conducted to minimize the flaws of the study, minimizing the risks of an experimental drug to the patients who were asked to participate in the research, and reporting results that were considered either "overly optimistic" or incorrect by their colleagues, in situations that put patients at risk. In several cases, scientists whose research methods or results have been questioned had a financial interest in the company that made the products they were evaluating.

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[54] Op. Cit. See footnote 50, p. 32450.

[55] Ibid., pp. 32450-1.

[56] Ibid., p. 32451.

These examples illustrate the diversity of ways that universities and Federal granting agencies have responded to allegations of scientific misconduct or conflict of interest. A few of the investigations described here were timely and thorough: the others were superficial, unfair, and/or very delayed. In several instances, making allegations against a colleague's work resulted in retaliation against the whistleblower.

RESOLVED CASES

A. CASE NO. 1: JOHN DARSEE, M.D., HARVARD UNIVERSITY

The First well known scientific fraud case of recent years involved Dr. John Darsee, a young cardiology researcher at Emory and Harvard.[57] In May 1981, in front of three Harvard coworkers, he fabricated research data for an experiment. For 5 months after Darsee had admitted his fraud to his supervisor and lab chief, they secretly investigated his work and found no further evidence of fraud.

At the time, Darsee was also working on another study, an NIH-funded project conducted at four, universities. In October 1981, NIH informed Harvard and the other three universities that NIH scientists had detected discrepancies in the research results. A few weeks later, Harvard informed NIH of Darsee's earlier admitted single act of fraud, which did not involve NIH research, and appointed a committee of

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[57] A summary of the Darsee case is included in *BioScience*, Vol. 33. June 1983, pp. 358-62.

five university, professors who conducted a second investigation. Harvard's report concluded that none of the published work Darsee conducted there contained fabricated data.

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pp. 28-38

. . . requests, they said, were hypocritical since Genentech had argued against the need for an advisory committee meeting for t-PA two years earlier, even though much less data were available on the effectiveness of t-PA, compared to data available on eminase.[150]

Genentech's influence on the scientific process has apparently continued. A new international study, known as ISIS-3, comparing t-PA, streptokinase, and the newly approved drug, eminase, is currently underway. Several American researchers have reported difficulty recruiting patients for the study, claiming that Genentech sales representatives have discouraged local cardiologists from referring patients to the study by making false statements about the inefficacy of eminase. These accusations are under investigation by the Food and Drug Administration.[151] Similarly, the company that makes eminase has asked the FDA to examine Genentech's promotional techniques, which

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[150] Ibid.

[151] Letter from D. John A. Lewis, St. Mary's Health Services, Grand Rapids, Michigan to Paul D. Parkman, Director. Biologics Evaluation and Research Center. FDA, April 9, 1990; this and related documents are available in subcommittee files.

they say include making invalid comparisons and misrepresenting published data, such as distributing a "survey" to doctors that implied that eminase could carry blood-borne diseases such as AIDS.[152]

F. CASE NO. 6: DR. CHARLES BLUESTONE AND THE PITTSBURGH MEDICAL SCHOOL

In April 1987, Dr. Erdem Cantekin made several formal allegations against Dr. Charles Bluestone, his colleague at the University of Pittsburgh Medical School, regarding research on drug treatment of children's middle ear infections (otitis media).[153] Every year, parents spend between $400 and $700 million on such treatment, despite medical controversies about the effectiveness of many of the drugs that are used.[154] Since 1980, the U.S. Department of Health and Human Services has provided $18.4 million in grants to the University of Pittsburgh Medical School's Otitis Media Research Center to carry out these studies; the pharmaceutical companies have also provided more than $3.5 million for some of the same research, and for related

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[152] Chase, M. (March 8, 1990). Battle of Heart-Attack Drugs Heats Up as SmithKline Decries Genetech Tactics. *The Wall Street Journal,* pp. B1, B8.

[153] Hearing, September 29, 1988, testimony of Dr. Erdem Cantekin, p. 15.

[154] Hearing, September 29, 1988, testimony of Dr. Erdem Cantekin, pp. 5-6.

studies.[155] Dr. Bluestone is the Director of the Otitis Media Research Center and the Principal Investigator on those grants.

Dr. Cantekin's main allegations were that Dr. Bluestone failed to disclose his private sources of research funding to NIH, as required on NIH grant applications; that Dr. Bluestone and his colleagues published articles claiming that ineffective drugs were effective; and that Dr. Bluestone and his colleagues at the Medical School and Children's Hospital of Pittsburgh prevented Dr. Cantekin from publishing his dissenting research results in a medical journal, by claiming exclusive rights to the NIH-funded data.[156]

The University of Pittsburgh Medical School appointed a committee of three faculty members to investigate Dr. Cantekin's charges. In June 1987, the committee concluded that the allegations had no "substance or validity."[157] Dr. Cantekin made a lengthy rebuttal of the committee's report in September 1987, but the Medical School did not respond.

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[155] Memorandum from Howard Hyatt, NIH, to Deputy Director, NIH, June 1, 1989. "Review of Allegations Involving the Otitis Media Research Center, Children's Hospital of Pittsburgh, in Hearing, June 13, 1989, p. 272.

[156] Hearing, September 29, 1988, testimony of Dr. Erdem Cantekin, pp. 9-25.

[157] The case is described in Hearing, September 29, 1988, testimony of Dr. Erdem Cantekin, pp. 9-25 and testimony of Dr. George Bernier, Dean of the University of Pittsburgh Medical School, pp. 88-89.

Dr. Cantekin brought his allegations to the attention of NIH in May 1987.[158] The National Institute of Neurological and Communicative disorders and Stroke (NINCDS), one of the NIH institutes, started an investigation of Dr. Bluestone's alleged failure to disclose private funding on his NIH grant applications.[159] The Medical School provided NIH with general information about the Medical School's investigation of Dr. Bluestone, and NIH halted the NINCDS investigation as soon as they were notified that the university's investigation had exonerated Dr. Bluestone.[160]

NIH continued to receive information about the university investigation but was otherwise inactive, explaining that they were waiting for the university to complete its inquiry. The NIH did not pursue its own investigation until after the Human Resources and Intergovernmental Relations Subcommittee held its first hearing on this case in September 1988.[161]

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[158] Hearing, September 29, 1988, testimony of Dr. Erdem Cantekin, p. 22.

[159] Hearing, September 29, 1988, documents on pp. 293-296.

[160] Ibid., testimony of Dr. Katherine Bick, pp. 193-194, 293-296.

[161] Hearing, September 29, 1988, testimony of Dr. James Wyngaarden, pp. 192-194.

9. *The University of Pittsburgh Medical School's Misconduct Investigation Erroneously Dismissed the Charges Against Dr. Bluestone*

The University of Pittsburgh Medical School's investigation of Dr. Bluestone consisted of interviews with Dr. Bluestone; the "whistle-blower," Dr. Cantekin; and several of their colleagues. The committee's conclusions indicate that they did not carefully review the documents that could have provided more objective information, not even those that Dr. Cantekin provided in his rebuttal to their report.

The Medical School investigation failed to agree with Dr. Cantekin on even the most obviously correct allegations. For example, Dr. Bluestone claimed that he always reported his private funding in his NIH grant proposals or progress reports, and the Medical School investigators and officials agreed; however, this in incorrect. As Dr. Cantekin alleged, in each NIH grant proposal and application for continued funding, Dr. Bluestone failed to report the funding he was receiving from pharmaceutical companies, as required in the grant proposal instructions. NIH instructions require a grantee to list all such research, to ensure that they are not receiving overlapping funds, or stretching themselves too thin by conducting too many studies at once. Dr. Bluestone has repeatedly claimed that this information was provided in the progress reports to NIH, but he admitted providing no information about 11 of the 35 privately-funded projects.

A review of the specific pages where Dr. Bluestone claims he reported funding for the 26 studies indicate that he is referring to *any mention of research* that received outside

funding, even in cases where there is *no mention of any funding sources.*[162] This is inconsistent with the instructions for the grant applications, which specify that the amount and source of funding must be disclosed. Of the 26 privately funded studies that he claims to have reported, the *sources* of funding were mentioned for 11; the other 15 studies were described, but Dr. Bluestone provided no information suggesting who funded these projects; in the context of the progress reports, this implied they were funded by the university. Moreover, he never reported the *amounts of funding* involved, which Dr. Bluestone later admitted totalled $3.5 million.[163] Only 9 of the 11 were correctly cited in each year of the grant applications.[164] Five of the funding sources were cited in 1986 or later, after Dr. Cantekin had begun to make allegations against Dr. Bluestone.

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[162] In his June 9, 1989, letter of complaint to Howard Hyatt at NIH, Dr. Bluestone stated "I did not claim we reported the 'dollar amounts of the funding' as stated in your report, but we did disclose the description of the non-NIH funded studies in our submissions, which disclosed the fact we had outside funding." This document is in Hearing. June 13, 1989, Appendix 4, p. 274.

[163] Memorandum from Howard Hyatt to Deputy Director of NIH, June 1, 1989, in Hearing, June 13, 1989, Appendix 4, p. 269.

[164] These statistics were compiled from documents available in subcommittee files and summarized in a staff memorandum presented in Hearing, June 13, 1989, Appendix 4, p. 278.

During the NINCDS investigation, Dr. Bluestone admitted that he stopped one NIH research project after studying only half the 1,000 children he had proposed to study, and then used the balance of the NIH funds to revise the study in a way that enabled him to receive more than $160,000 in research funding from two pharmaceutical companies in addition to the funding from NIH. Dr. Bluestone failed to report the drug company funding to NIH in his progress report, as required. When Dr. Bluestone admitted this to NIH in 1987, he said it was an oversight; even then, he neglected to specify exactly how much money was provided by the drug companies.[165] Despite this admission of wrongdoing, which was consistent with Dr. Cantekin's allegations, the Medical School investigators dismissed Cantekin's claim as erroneous.

In addition to the research funding from private industry, Dr. Bluestone received more than $50,000 each year in honoraria from private industry, most of it in the form of speaking fees from three of the pharmaceutical companies involved in the studies. In addition, the pharmaceutical companies paid Dr. Bluestone more than $25,000 every year for the past few years for travel expenses, for speeches across the country and around the world. Dr. Cantekin had made accusations of potential conflicts of interest to the Medical School; however, the Medical School did not review the accuracy of Dr. Cantekin's accusations, although they had access to the information. These industry payments are not

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[165] Letter from Dr. Charles Bluestone to Dr. Earleen Elkins, June 23, 1987; in Hearing, September 29, 1988, Appendix 3, pp. 244, 247-248.

restricted by the Medical School or NIH, but Dr. Cantekin questioned whether the financial ties biased Dr. Bluestone's research results.

Dr. Cantekin was also correct when he alleged that in their research, Dr. Bluestone and his colleagues did not diagnose children's ear infections as they had said they would in their NIH grant proposal, and instead analyzed it in a way that made the drug under study look more efficacious. Whether the researchers' judgment was correct in revising the diagnostic protocol is a scientific judgment; however, Bluestone's change in the diagnostic algorithm was an objective fact that was incorrectly denied by the Medical School investigative committee, based on Dr. Bluestone's denial (which he later retracted).

The university also failed to examine apparent bias in the conclusions of Dr. Bluestone's published research. The NIH grantees reported that the drug was completely ineffective for treating hearing loss and that more than half the ear infections that were "cured" at 2 weeks had recurred within 6 weeks.[166] However, these findings were not mentioned in the conclusions of the published article or in later claims by the researchers that the drug was effective. This was a serious omission, since the recurrence of these ear

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[166] Mandel, E.M., Rockette, H.E., Bluestone, C.D., Paradise, J.L., & Nozza, R.J. (1987). Efficacy of Amoxicillin With or Without Decongestant-Antihistamine for Otitis Media With Effusion in Children. *New England Journal of Medicine*, Vol. 316, pp. 432-437.

infections is a major problem, and since hearing loss is the primary danger of this type of ear infection.

10. The University of Pittsburgh Medical School Prevented Dr. Cantekin From Publishing His Analysis of the Research Results

Dr. Cantekin was also correct in his allegations that officials of the University of Pittsburgh Medical School and the Children's Hospital of Pittsburgh discouraged the *New England Journal of Medicine* from publishing an article based on the results of Dr. Cantekin's revised data analysis, which concluded that the drug under study was not effective. The officials notified the editor that Dr. Cantekin was not authorized to publish the data, and that he had been found guilty of misconduct himself.[167]

Dr. Cantekin's other allegations regarding Dr. Bluestone's limiting access to data were also supported by the subcommittee investigation, although dismissed by the Medical School investigation. For example, Dr. Cantekin claimed that his computerized data tape was taken from him, whereas Dr. Bluestone and his colleague claimed that Dr. Cantekin's data were merely moved from one data tape to

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[167] Letter to Dr. Arnold Relman, Editor of *The New England Journal of Medicine,* from Dr. William F. Donaldson, Medical Director of Children's Hospital of Pittsburgh. Dr. Edwin Zechman, President of Children's Hospital of Pittsburgh, and Dr. Eugene Myers, Professor, University of Pittsburgh School of Medicine, August 1, 1986; in Hearing, September 29, 1988, Appendix 4, pp. 253-255.

another, that they were still available to him upon request, and that the moving of the data was not the decision of Dr. Bluestone.[168] However, an engineer working on the project notified the subcommittee that he removed the data from Cantekin's hard disk on the direct orders of Dr. Bluestone. The data were not made available to Dr. Cantekin for more than two years, and when they were made available in 1989 as part of the university's hearing procedure, Dr. Cantekin was notified that he could not use the data in any publications because they were owned by the university.[169]

11. Pittsburgh Medical School Retaliated Against the Whistleblower by Filing Counter Charges of Misconduct Against Him

Ironically, after the initial investigative committee denied that the Medical School tried to prevent Dr. Cantekin from analyzing or publishing his data, a subsequent Pittsburgh Medical School investigative committee found Cantekin guilty of misconduct for trying to publish those data. After concluding that his allegations against Dr. Bluestone were without merit, the Chairman of the Department accused Dr. Cantekin of misconduct, defined in part as making baseless

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[168] A summary of this issue is presented in Dr. Cantekin's prepared statement in the September 29, 1988, Hearing and in Dr. George Bernier's testimony on p. 92 of that Hearing; details are presented in the Hearing, Appendix 3, pp. 256-257, and in other supporting documents that are available in subcommittee files.

[169] Hearing, September 29, 1988, Appendix 3, pp. 256-257.

accusations against his colleagues, and attempting to publish his dissenting version of the research he had questioned.[170]

A major issue that is raised by the allegations against Dr. Cantekin is the question of who has the right to publish federally-funded research data. In most cases, "ownership" of data has to do with who received funding to conduct the research. Federal grants are awarded to an eligible university or nonprofit organization, but there is always a "Principal Investigator"who is the individual designated as responsible for the research project. In this case, the Principal Investigator was accused of misrepresenting data by a co-investigator on the grant, and blocked the co-investigator from publishing his version of the research results.

The Medical School's claim of data ownership rights, and the denial of Dr. Cantekin's rights to publish dissenting results, are inconsistent with the stated position of NIH that the research data that they fund should be shared with other researchers.[171] Similarly, Dr. George Lundberg, editor of the *Journal of the American Medical Association,* testified that since "the public interest comes first there, and the institution's interest is way down the line," researchers should have the right to publish dissenting results of federally-funded

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[170] The allegations against Dr. Cantekin also included other authorship issues, which were later dismissed by the Medical School and NIH. Documents regarding these other allegations are available in Pittsburgh Medical School documents and NIH documents that are available in subcommittee files.

[171] Hearing, June 13, 1989, testimony of Dr. James Wyngaarden, p. 195.

biomedical research.[172] From the editor's point of view, Dr. Lundberg testified that "the journal should receive whatever manuscripts it receives in good faith, proceed with the review process, and in the interest of the public, publish the most truthful, important articles possible without being particularly concerned as to what the institutional politics might be."[173]

In February 1989, the Dean of the Medical School empaneled a hearing board to consider the accusations against Dr. Cantekin. The Board concluded that "Dr. Cantekin, not Dr. Bluestone, had behaved in direct violation of accepted professional, ethical, and collegial standards of the university" by trying to "derail the publications of his colleagues."[174]

Dr. Cantekin appealed the findings against him, and another panel of experts was appointed to consider the appeal. Meanwhile, on March 26, 1990, Dr. Cantekin received notification from Children's Hospital that "Because of the renovation plans of the Hospital, to accommodate new and expanding services, it has become necessary to relocate your office" from the hospital to a windowless room above a

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[172] Hearing, June 13, 1989, testimony of Dr. George Lundberg, Editor of *JAMA*, p. 80.

[173] Ibid., p. 80.

[174] Letter from George Bernier, Dean of the University of Pittsburgh Medical School, April 20, 1989, with accompanying report; in Hearing, June 13, 1989, pp. 251-254.

supermarket.[175] Dr. Cantekin protested this move, and on March 27, 1990, the General Counsel of the University assured Cantekin's lawyer that the move would not take place. However, the following morning, security personnel broke into Dr. Cantekin's office, packed his belongings, and moved them to the Giant Eagle supermarket.[176]

On April 11, 1990, the President of the University of Pittsburgh accepted the recommendation of an appeals panel composed of university faculty that found Dr. Cantekin guilty of misconduct for his attempts to publish the article describing the antibiotics as ineffective in the treatment of otitis media with effusion. Of the five faculty members of the panel, four found him guilty.[177] The fifth dissented from the panel conclusions, because Dr. Cantekin had notified Dr. Bluestone and his other colleagues of his efforts to publish his paper and invited them to be co-authors, and had notified the scientific journal where he had submitted his manuscript that this article was based on the same data described in their previously reviewed article by Dr. Bluestone and his colleagues.

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[175] Letter from William F. Donaldson, Medical Director, Children's Hospital, to Dr. Erdem Cantekin, March 26, 1990; in subcommittee files. The description of the office as "windowless" is included in a letter from Dr. Cantekin to President Posvar, June 15, 1990; available in subcommittee files.

[176] Steele, B., Decision made, but not disclosed on Cantekin, *University Times*. April 26, 1990. pp. 1, 4; in subcommittee files.

[177] All documents described in this paragraph are available in subcommittee files.

In their review of Dr. Cantekin's publication efforts, neither the faculty panel, the Medical School administrators, nor the university president questioned whether the university that receives Federal funds has a responsibility to permit publication of federally-funded research results, in cases where co-investigators disagree with the findings of the principal investigator.

In April 1990, the Dean of the Medical School recommended that Cantekin's tenure be revoked as a result of the university's findings against him.[178] The removal of tenure, which is necessary in order to fire a tenured professor, must be approved by a faculty committee and by the President of the university. However, on May 11, Dr. Thomas Detre, President of the Medical and Health Care Division of the Medical School, wrote to the President of the university, stating that although "there are sufficient findings of fact to support Dr. Cantekin's tenure revocation," he recommended that Dr. Cantekin be placed on probation instead because of current controversies regarding data ownership and related issues.[179] Dr. Wesley Posvar, President of the University of Pittsburgh, agreed to put Dr. Cantekin on probation for 5 years, during which a committee would periodically assess his "behavior and conduct"; moreover, the Dean of the School of Medicine could at any time recommend "further disciplinary

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[178] Letter from George Bernier, Dean of the University of Pittsburgh Medical School, to Dr. Erdem Cantekin, April 24, 1990; available in subcommittee files.

[179] Letter from Dr. Detre to Dr. Posvar, May 11, 1990; available in subcommittee files.

action, including revocation of tenure" based upon allegations from other sources.[180]

NIH has started a preliminary inquiry into the university's charges against Dr. Cantekin, but no formal NIH investigation has been initiated. Although the allegations had not been resolved, NIH awarded a grant of $1.7 million to Dr. Bluestone on November 29, 1989.[181]

12. Despite Conclusive Evidence of Wrongdoing, NIH Has Defended Dr. Bluestone's Failure to Disclose Non-Federal Research Funds on His NIH Grant Applications

When the university failed to comprehensively investigate his charges, Dr. Cantekin asked NIH for assistance. The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), which was the institute providing funding for the research, started their own investigation.[182] However, this investigation was very limited compared to the accusations made by Dr. Cantekin; NINCDS focused on the question of *overlap* of NIH and drug company research funding, rather than *nondisclosure* of information and misrepresentation of data. The NINCDS

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[180] Ibid. Letter from Wesley Posvar, President of the University of Pittsburgh, to Erdem Cantekin, May 18, 1990; available in subcommittee files.

[181] The notice of this award is in subcommittee files.

[182] Hearing, September 29, 1988, testimony of Dr. Bick, p. 194; Appenidx 3, pp. 243-249.

investigator reported trying to meet with the NIH fraud office, but explained that the planned meetings were cancelled by the fraud officer. When NIH subsequently received official word that the University of Pittsburgh Medical School had exonerated Dr. Bluestone, NIH stopped its own investigation.[183]

When the issue of failure to disclose research funds from private industry was first raised by Dr. Cantekin, NIH defended Dr. Bluestone by saying that there was overlapping funding on only one project.[184] When the subcommittee raised the issue at its hearing, NIH officials again defended Dr. Bluestone, this time erroneously claiming that the private funding sources had been disclosed in the progress reports, and testifying that they did not realize that the specific levels of private funding had not been disclosed anywhere on the grant applications or progress reports.[185]

After the first public hearing on the topic, the subcommittee provided evidence to the NIH, to Dr. Bluestone, and to the University of Pittsburgh Medical School regarding Dr. Bluestone's failure to report more than $3.5 million in research funds from drug companies on his applications for NIH grants. In a subsequent report and at the next Congressional hearing examining this case, NIH agreed with the subcommittee that the information about private

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[183] Ibid., testimony of Dr. Katherine Bick, pp. 193-194, 293-296.

[184] Hearing, September 29, 1988, pp. 193 and 195.

[185] Ibid., pp. 192-193.

funding had not been provided on the grant applications or renewals, but defended Dr. Bluestone by claiming that the grant application instructions were unclear until 1985.[186]

NIH officials claimed that prior to 1985, the instructions read "List all research support for each individual including requests now being considered, as well as any proposals being planned, regardless of relevance to this application. Include also current or pending contracts, fellowship awards, research career program awards, training grants, regardless of the source of support. List grant number, total funds for the entire project period, estimated percentage of effort the individual devotes to the project, and the source of the support."[187] NIH apparently considered these instructions vague because they did not specifically define the requirement of listing "all" sources of funding as including "non-Federal" sources of funding.

However, NIH officials were incorrect in describing the content of the NIH forms; the section regarding "Other support" was revised in late 1979 and revised forms, containing the more explicit language, were available to applicants in 1980 or 1981, depending on the type of application. For example, in September 1980, the instructions for applicants applying for continuation of a research grant,

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[186] Hearing, June 13, 1989, testimony of Dr. Earleen Elkins, p. 206 and testimony of Dr. James Wyngaarden, p. 209.

[187] Memorandum from Howard Hyatt, Director of the Division of Management Survey and Review, to the Deputy Director of NIH, June 1, 1989; in Hearing, June 13, 1989, Appendix 4.p. 268.

including Dr. Bluestone, specified that the applicant should "List by source, project title, and annual amount other Federal or non-federal research support for the principal investigator and other professional personnel key to the project during the budget period."[188]

Despite claims by NIH and Dr. Bluestone that he did not understand the grant application instructions, and therefore inadvertently failed to include the necessary funding information, colleagues who were key personnel on the same Otitis Media Research Center grant apparently did understand the instructions, because they correctly listed their *non-Federal* grants in Dr. Bluestone's grant application. For example, in their application for 1985-1990, one of the co-investigators, Dr. Robert Nozza, listed a $7,000 grant from the Pennsylvania Lions Hearing Research Foundation and $10,000 from the Deafness Research Foundation.[189]

In contrast to the NIH justifications of why Dr. Bluestone did *not* disclose the funding he received from drug companies, Dr. Bluestone and the Medical School officials continue to make the erroneous claim that he *did* disclose his other sources of funding. Although they admit that the disclosure was not made at the appropriate place on the grant application, Dr. Bluestone protested the NIH findings that the Otitis Media Research Center "has generally not disclosed to

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[188] A copy of these and similar instructions are in Hearing, June 13, 1989, Appendix 4, pp. 296-300.

[189] A copy of this page from the application for continued funding is provided in Hearing, June 13, 1990, Appendix 4, p. 300.

NIH the extent of its industry-sponsored research," falsely claiming that he had made the information available in his NIH progress reports.[190]

13. *NIH's Initial Investigation of the Allegations of Misrepresented Research Results Regarding Children's Ear Infections Was Grossly Inadequate*

The most important allegations made by Dr. Cantekin was that Dr. Bluestone tended to report only those research findings that were favorable to the drug companies that supported him. During the nine months following the first subcommittee hearing on this matter, NIH investigated that allegation by reviewing 50 studies supported by outside sources. Twenty-seven of those studies had results that NIH investigators categorized as positive, negative, or neutral. The investigators concluded that 12 study results were positive, 10 were negative, and 5 were neutral.

On the basis of those simple categories, NIH concluded that there was no apparent conflict of interest, because the number of positive and negative outcomes were similar, although "[i]n a few of the marginally positive studies, however, there appeared to be a tendency to be

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[190] Memorandum from Howard Hyatt, Director of the Division of Management Survey and Review, to the Depurty Director of NIH, June 1, 1989; and letter from Charles Bluestone to Howard Hyatt, June 9, 1989; in Hearing, June 13, 1989, Appendix 4, pp. 267-275.

optimistic and recommend further testing."[191] In support of allegations of failure to publish some research findings, especially those with a negative impact on the drug companies that supported him, NIH also found that of the 12 studies that had not yet been published, two studies involving clinical trials of children "should have been completed and published by now."[192]

Based on those findings, NIH concluded that "this analysis shows that Dr. Bluestone did not report only the result of studies which were favorable to the pharmaceutical companies that sponsored this research. . . . we cannot conclude that he showed favorable bias toward drug companies in the reporting of his research results."[193]

The NIH is correct that they cannot draw conclusions regarding bias based on their analysis; unfortunately, they did not analyze the data in a way that would enable them to determine bias, whether or not bias existed. For example, for one of Dr. Bluestone's unpublished studies, statistical analyses conducted by the subcommittee found that three

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[191] Memorandum from Howard Hyatt, Director of the Division of Management Survey and Review, to the Deputy Director of NIH, June 1, 1989; in Hearing, June 13, 1989. Appendix 4. p. 271.

[192] Ibid., p. 270.

[193] Memorandum from Howard Hyatt, Director of the Division of Management Survey and Review, to the Deupty Director of NIH, June 1, 1989; in Hearing, June 13, 1989. Appendix 4. p. 271.

drugs that Dr. Bluestone had reported to NIH to be more effective than placebo were actually no more effective than the placebo in the second phase of the study.[194] NIH did not conduct any reanalyses of data, or even examine the types of analyses conducted by the principal investigator.

In a later analysis, conducted in 1990, NIH more carefully analyzed a small number of these studies, and concluded that Dr. Bluestone and his colleagues tended to not evaluate the "biological significance of their data," resulting in reports that were "less than objective."[195]

However, in March 1990, an international group of researchers published the results of a study of more than 3,600 children with ear infections, whose findings are consistent with Dr. Cantekin's allegations, and in direct contradiction to those published by Dr. Bluestone and his

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[194] Dr. Bluestone found that amoxicillin was significantly more effective than placebo in the first phase of the study; that is the phase whose methodology is questioned by Dr. Cantekin. Dr. Bluestone found no difference between the placebo and amoxicillin or two other drugs in the second phase of the study. However, he combined the data from the second phase with that of the questionable first phase, and the results for the combined sample showed a significant difference for the antibiotics. These analyses are presented in Hearing, June 13, 1989, pp. 282-294.

[195] A panel of experts has been examining scientific questions since late 1989 according to a letter from Dr. William Raub, Deputy Director of NIH, to Chairman Weiss, October 18, 1989; in Hearing, June 13, 1989, Appendix 4, p. 307. A July 1990 draft of the final report is in subcommittee files.

colleagues.[196] The researchers found that antibiotics were not effective for treatment, and that rates of recovery were *higher* for patients who did not receive antibiotics.[197] The researchers also claimed that since "an expert in otitis media in the United States recommends 10 day's treatment" with antibiotics, 92 percent of the U.S. doctors in the study prescribed 10 days, compared to a typical course of 5 days in Great Britain.

Although the international study does not prove that Dr. Bluestone and his colleagues misrepresented their research results, this major study's findings lend impressive support to Dr. Cantekin's dissenting research results. Similar evidence of the ineffectiveness of antibiotics would have been available to physicians and the public several years ago, if the Medical School had not prevented Dr. Cantekin from publishing them.

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[196] Dr. Cantekin's allegations focused on studies of secretory otitis media, but he also questioned Dr. Bluestone's research on acute otitis media. These questions are now supported by the results of this international study of more than 3,600 children, cited in Froom, J. *et al.* (March 3, 1990). Diagnosis and antibiotic treatment of acute otitis media: Report from International Primary Care Network, *British Medical Journal,* Vol. 300, pp. 582-586.

[197] The study was conducted in nine countries, including Australia, Belgium, Canada, Great Britain, Israel, the Netherlands, New Zealand, Switzerland, and the United States.

14. NIH Delayed Its Investigation Regarding Dr. Bluestone for More Than 3 Years After Allegations Were Made, and Continued to Fund His Multi-Million Dollar Projects

It is NIH policy to rely on the university grantee to conduct the initial investigation. NIH generally does not initiate its own "preliminary inquiry" until after the university investigation is completed.

By the time of the subcommittee hearing in September 1988, the University of Pittsburgh Medical School had completed their investigation of Dr. Cantekin's allegations and concluded that they were without merit. Instead, they were investigating the counter-allegations against Dr. Cantekin, made by Dr. Bluestone and others in the Department. However, Dr. Katherine Bick, NIH Deputy Director for Extramural Research, testified that she had persuaded the Medical School Dean that their ongoing investigation should include the allegations made *by* Dr. Cantekin, in addition to those *against* him.[198] Therefore, Dr. Bick testified that NIH would not initiate their investigation until the Medical School's investigation of Dr. Cantekin's allegations was completed. Despite the Dean's promise that they would reopen the investigation of Dr. Cantekin's allegations, for the almost 2 years since then, the university continued to focus exclusively on the allegations *against* Dr. Cantekin rather than those he had made against Dr. Bluestone.

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[198] Hearing, September 29, 1988, testimony of Dr. Katherine Bick, p. 200.

They had already closed the case involving allegations against Dr. Bluestone.

NIH delayed initiating even their preliminary inquiry until the Medical School's counter investigation *against Dr.* Cantekin was completed. Since the university was investigating Dr. Cantekin rather than Dr. Bluestone, the NIH decision to delay its inquiry regarding Dr. Bluestone was inappropriate even by their own standards.

The result of the delay was that Dr. Cantekin, who first brought his allegations to NIH's attention in 1987, has been unable to conduct research at the university for 4 years, while waiting for the NIH to decide whether or not to even initiate a formal investigation of his charges.

In addition, the NIH has failed to review the specific issue of whether Dr. Cantekin has a right to public a scientific article based on his analysis of the data gathered with NIH funds. In testimony and internal documents, NIH officials questioned Dr. Cantekin's role in the otitis media research, incorrectly stating that he was not a co-investigator.[199] As a result of the Pittsburgh Medical School's actions blocking publication of Cantekin's findings, and the NIH's inaction, Dr. Cantekin's results have not been published.

During the period when NIH Finally initiated its preliminary inquiry regarding Dr. Bluestone, the Medical School found Dr. Cantekin to be guilty of misconduct for

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[199] Hearing, June 13, 1989, testimony of Dr. Wyngaarden, p. 198.

trying to publish his findings. The Medical School's conclusions are based on their assumption that the Medical School determines who has the right to publish the data from a federally-funded study; this assumption has not been evaluated by NIH and appears inconsistent with Federal policies supporting data sharing.[200] Meanwhile, Dr. Bluestone made formal allegations of misconduct to NIH against Dr. Cantekin, claiming that Dr. Cantekin had manipulated research data in order to find antibiotics ineffective for children's ear infections.[201] NIH is currently conducting a preliminary inquiry of the allegations against Dr. Bluestone, and the counter allegations against Dr. Cantekin. NIH has continued to fund Dr. Bluestone throughout the years of allegations against him, and in late 1989 decided to renew his funding for an additional $1.7 million.[202]

In their July 1990 final draft report, based on their "preliminary inquiry," the Public Health Service Office of Scientific Integrity concluded that Dr. Bluestone's reporting of research results was "less than objective" in describing the efficacy of antibiotics for children's ear infections.[203] However, OSI concluded that a misconduct investigation was

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[200] This issue will be discussed in greater detail later in the report.

[201] Letter from Charles Bluestone to OSI, July 14, 1989; in subcommittee files.

[202] The grant documents are available in subcommittee files.

[203] The draft report is in subcommittee files.

not needed, and agreed with the Pittsburgh Medical School that Dr. Cantekin's attempts to publish his dissenting views were inappropriate. NIH did not question the Medical School's retaliatory behavior against the whistleblower, or the university's claim of data ownership of the NIH-funded research.